



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F2844 - Pendimethalin (Prowl®) on Safflower Seeds.

Review of the July 30, 1990 Amendment.
(No MRID Number) [DEB Nos. 7049 and 7050]
{HED Project No. 0-1931}

FROM: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

TO: Robert J. Taylor, PM-25
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch - Herbicide, Fungicide, and
Antimicrobial Support
Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

American Cyanamid Company has submitted this amendment consisting of a cover letter and a new Section B (new directions for use of Prowl® on safflower seeds) in response to deficiencies outlined in the Residue Chemistry Chapter of the Pendimethalin Registration Standard dated May 10, 1984 and the Pendimethalin Registration Standard Update of March 19, 1990. CBTS (aka RCB) had previously recommended for the requested tolerance of pendimethalin on/in safflower seeds (see memo PP#3F2844, K.H. Arne, July 6, 1983); however, the Pendimethalin Registration Standard was issued before the tolerance was established. The Standard identified a number of residue chemistry deficiencies, thus preventing establishment of the proposed tolerance. In his cover letter, the petitioner requests reactivation of the petition contending all major TOX deficiencies are resolved. The deficiencies identified in the Registration Standard are repeated below in the body of this review in the order they appeared in the Pendimethalin Registration Standard followed by the petitioner's response, and then CBTS comments. Our conclusions and recommendation follow.

EXECUTIVE SUMMARY OF CHEMISTRY DEFICIENCIES

- Plant metabolism studies required.
- Poultry metabolism studies are necessary.
- Ruminant metabolism study characterization of residues is required.
- Confirmatory analytical method needed.
- Multiresidue method (MRM) data are needed.
- Livestock feeding studies may be required.
- Safflower seeds processing study should be repeated.

CONCLUSIONS

1. CBTS Conclusion on Directions for Use

The petitioner has proposed an adequate set of directions for use of Prowl® Herbicide (EPA Registration No. 241-243) on safflower seed fields to control various grasses and broadleaf weeds.

2. CBTS Conclusion on Nature of the Residue - Plants

CBTS reiterates that the nature of the residue in plants is not adequately understood. Additional plant metabolism studies are required in which pendimethalin, radiolabeled in the phenyl ring, is applied to plants at rates equal to or greater than the maximum application rate. High application rates, provided there is no phytotoxicity, are preferred to increase the level of radioactive material available for analysis and identification. One plant metabolism study should be conducted on sweet corn with analysis of vegetative parts and grain from 1) plants treated preemergence and 2) plants treated postemergence. A second plant metabolism study is needed on a plant in which the edible portion grows in the soil. The deficiency remains unresolved and continues outstanding.

3. CBTS Conclusions on Nature of the Residue - Livestock

a. CBTS reiterates that the ruminant metabolism study submitted in a co-pending petition does not define the nature of the residue. Measurable/detectable residues were found only in the caprine liver ranging from 0.08 ppm to 0.17 ppm from a 6.5 ppm dose of ^{13}C and ring labeled ^{14}C -pendimethalin. Fractionation of the liver extracts revealed numerous free, unbound ^{14}C -components which were not characterized. CB reiterates the petitioner has not

adequately characterized the nature of the residue in ruminants. CB suggests the petitioner repeat the HPLC identification step for all fractions containing 0.005 ppm radiolabeled residues characterizing major peaks using detectors that can elucidate organic structure using detectors such as but not limited to MS, FTIR, FTUV, NMR, etc. The petitioner needs to confirm the presence of or absence of all metabolites identified in the rat metabolism study. Complete identification of the caprine radiolabeled residue is essential for CB to ascertain the need for a ruminant feeding study. CBTS reminds the petitioner that if the ruminant metabolism is found to differ significantly from that in rats, then porcine ^{14}C -pendimethalin metabolism data are also necessary. This deficiency is not resolved and continues outstanding.

b. CBTS reiterates that poultry metabolism studies are required using laying hens dosed with ring labeled ^{14}C -pendimethalin for at least 3 days at a level greater than 1 ppm, preferably 10 ppm, sufficient to have adequate radiolabeled material available for identification. The laying hens are to be sacrificed within 24 hours of the final dose. The distribution and characterization of at least 90 percent of the radiolabeled residue need to be determined in eggs (white and yolk), muscle, fat, skin, and liver. The deficiency is not resolved and continues outstanding.

4. CBTS Conclusion on Residue Analytical Method

a. CBTS reiterates that a validated confirmatory method (Mass Spec is suggested) for residues of pendimethalin, per se, and its metabolite CL-202,347 is necessary. The deficiency is not resolved and continues outstanding.

b. CB reiterates additional multiresidue method (MRM) validation data are necessary for FDA MRM's A thru E. Chromatographic data are required for pendimethalin and its alcohol metabolite for protocol C. Representative samples of plant and animal tissues need to be analyzed by MRM protocols B, D, and E following FDA's Decision Tree for MRM testing. The protocols are found in FDA's PAM Vol-I, Appendix II. The deficiency is not resolved and continues outstanding.

c. CB reiterates if radiolabeled validation of existing analytical methods for plants and animal tissues indicates a major portion of the total radioactive residue is not recovered and identified by these methods, then radiolabeled validation of any new proposed residue analytical method(s) may be required. The deficiency is not resolved and continues outstanding.

5. CBTS Conclusion on Storage Stability Data

CBTS reiterates that data are needed reflecting the stability of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (CL-202,347) in or on representative plants [such as root and tuber vegetables, legume vegetables, cereal grains, and miscellaneous crops (cottonseed, peanuts, and sunflower/safflower seeds)] and animal samples stored at freezing temperatures for time intervals approximating those of the treated samples used to determine the magnitude of the residue. The sample storage conditions and intervals need to be supplied for all previously submitted data for safflower commodities (raw and processed foods and feeds). Storage stability are required for only those samples deemed to be useful for tolerance assessment. The purity of the reference standards used for fortification of samples and a complete description of the analytical method (including extraction procedures) and any method validation data generated need to be presented. The deficiency is not resolved and continues outstanding.

6. CBTS Conclusion on Magnitude of the Residue - Crop Field Trials

CBTS reiterates that when Prowl® Herbicide is used as directed and at exaggerated application rates of 1.3X no residues of pendimethalin and its alcohol metabolite were detected at or above the limit of detection, 0.05 ppm. There are adequate crop field trial data to show that when Prowl® Herbicide is used as directed residues of pendimethalin and its metabolite are not expected to exceed the proposed tolerance.

7. CBTS Conclusions on Magnitude of the Residue - Meat/Milk/Poultry/Eggs

a. CBTS reiterates that a conventional ruminant feeding study may be necessary, depending on the results of the ruminant metabolism study, in which lactating ruminants are dosed at 0.1, 0.3, and 1.0 ppm pendimethalin, per se, in the total diet, greater than or equal to three animals per dose group. The animals should be kept on the treated feed for 4 weeks. However, if residues have not plateaued in milk by the end of 4 weeks, then the feeding period should continue until a plateau is reached. Milk should be collected twice daily and residues determined therein. Animals must be sacrificed within 24 hours of the final dose and residues determined in muscle, liver, kidney, and fat. The deficiency is not resolved and continues outstanding.

b. CBTS reiterates that a conventional poultry feeding study may be necessary, depending on the results of the poultry metabolism study, in which laying hens are dosed at 0.1, 0.3, and 1.0 ppm pendimethalin, per se, in the total diet, greater than or equal to 10 hens per dose group. The

laying hens should be kept on the treated feed for 4 weeks. However, if residues have not plateaued in eggs by the end of 4 weeks, then the feeding period should continue until a plateau is reached. Eggs should be collected at least daily and residues determined therein. The laying hens need to be sacrificed within 24 hours of the final dose and residues determined in muscles, liver, and fat. The deficiency is not resolved and continues outstanding.

c. CBTS reiterates that the nature of the pendimethalin residues in livestock is not adequately understood. If the feeding studies are necessary, at this time CBTS reiterates that we will request residue data for residues of pendimethalin, per se, and its metabolite CL-202,347 in the conventional feeding studies. CBTS points out that residue data may need to be presented for any additional metabolite(s) of toxicological concern if the requested metabolism studies so identify them.

d. CBTS reiterates that the present ruminant metabolism study indicates that residues of pendimethalin may occur in meat and meat by-products. The petitioner should be advised that tolerances need to be proposed for these food commodities if the requested pendimethalin metabolism and feeding studies so indicate the transfer of residues. The deficiency is not resolved and continues outstanding.

8. CBTS Conclusion on Magnitude of the Residue - Processed Food/Feed

The petitioner needs to repeat the pendimethalin safflower processing study using treated safflower seeds bearing detectable residues or if no residues are detected, then use safflower seeds treated at the highest practical application rate. The safflower seeds are to be processed by standard commercial operations into safflower meal, crude and refined safflower oils. Pendimethalin and its metabolite residue data are needed for each of these processed safflower commodities. If pendimethalin residues concentrate, then the appropriate food and/or feed additive tolerances need to be proposed.

RECOMMENDATION

CBTS cannot recommend, at this time, for the requested pendimethalin tolerance at 0.1 ppm on safflower seed for the reasons cited above in our Executive Summary of Deficiencies and detailed in our Conclusions 2 through 7.

For further consideration of this petition, the petitioner needs to be advised to resolve these deficiencies.

DETAILED CONSIDERATIONS

Directions for Use

Petitioner's Response

The petitioner has presented a revised label for use of Prowl® Herbicide (EPA Registration No. 241-243) containing 4 lb active ingredient (a.i.)/gal (42.3%) of technical pendimethalin to control various grasses; e.g., barnyard grass, crabgrass, foxtail, Johnsongrass, etc., and broadleaf weeds; e.g., carpetweed, lambsquarter, pigweed, etc., in safflower seed production.

CBTS Comments

The petitioner proposes applying Prowl® Herbicide preplant, in at least 10 gallons water by ground application or in at least 5 gallons water by aerial application. The rate of application in Southern States where there are no organic matter in soil restrictions, ranges from 1 pint (0.5 lb ai pendimethalin) per acre in coarse sandy soils to 3 pints (1.5 lb ai) per acre in fine clay soils. In Northern States, with soils containing 3 percent organic matter or less, the Prowl® application rate ranges from 1 pint (0.5 lb ai pendimethalin) per acre in coarse sandy soils to 3 pints (1.5 lb ai) per acre in fine clay soils. When Northern coarse soils contain more than 3 percent organic, the Prowl® application rate ranging from 2 pints (1.0 lb ai) per acre in coarse sandy soils to 3 pints (1.5 lbs ai) per acre in fine clay soils. For safflower seed fields, Prowl® is mechanically incorporated into the fields within 7 days of application into the top 1 or 2 inches of soil. There are rotational crop restrictions for winter barley and wheat, sugar and red beets, and spinach.

The petitioner has proposed an adequate set of directions for use of Prowl® Herbicide on safflower seed fields.

NATURE OF THE RESIDUE - PLANTS

Deficiency

The following additional data are required:

- o Data involving the reasonably complete characterization of the extractable and unextractable radioactive residues found in plant tissues as the result of the application of radiolabeled pendimethalin in a manner simulating a treatment regime registered for use. Representative crops (potatoes, soybeans, corn, etc.) for which pendimethalin formations are registered should be used.

Petitioner's Response

The petitioner did not respond.

CBTS Comments

After a number of consultations with the petitioner, CBTS reiterates that the registrant should be informed that the plant metabolism data base for pendimethalin is not adequate. Although the available studies indicate that low levels of radioactivity are taken up from the soil into aerial parts of plants, these studies were conducted with pendimethalin radiolabeled in side chains as opposed to the phenyl ring. In addition, most of the studies were conducted using application rates lower than the maximum permitted on product labels.

Additional plant metabolism studies are required in which pendimethalin, radiolabeled in the phenyl ring, is applied to plants at rates equal to at least the maximum rates on product labels. Provided significant phytotoxicity does not occur, even higher application rates (2X to 5X) are preferred to increase the level of radioactivity available for analysis and identification. One study should be conducted on sweet corn with analysis of vegetative parts and grain from 1) plants treated preemergence and 2) plants treated postemergence. A second plant metabolism study is needed on a plant in which the edible portion grows in the soil, e.g., potatoes or peanuts. The petitioner's report is expected to include percent total radioactive residue (TRR) as well as ppm values for each fraction. The petitioner is expected to confirm identities of all metabolites by a second technique.

Chemistry Branch I recently concluded that deficiencies in the knowledge of plant metabolism were not applicable for use on sugarcane (PP#2F2765, R. Cook, 11/26/90). CBTS emphasizes that this decision applies only to sugarcane and is based on the low total activity (< 0.01 ppm) and long preharvest interval observed in that crop.

CBTS reiterates that the nature of the residue in plants is not adequately understood. This deficiency continues unresolved and remains outstanding.

NATURE OF THE RESIDUE - LIVESTOCK

Deficiencies

The following data are required:

o Metabolism studies utilizing ruminants. Animals must be dosed with ring-labeled [¹⁴C]pendimethalin for 3 days at a level (> 1.5 ppm) sufficient to make residue identification possible. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk,

muscle, fat, kidney, and liver. If ruminant metabolism is found to differ significantly from that in rats, then swine metabolism data will also be required.

o Metabolism studies utilizing poultry. Hens must be dosed with ring-labeled [¹⁴C]pendimethalin for 3 days at a level (> 1 ppm) sufficient to effect residue identification. Birds must be sacrificed within 24 hours of the final dose. Residues must be characterized and quantified in eggs, muscle, fat, kidney, skin, and liver.

o Metabolism studies utilizing ruminants and poultry. Animals must be dosed orally with ring-labeled ¹⁴C-pendimethalin for a minimum of 3 days at a level sufficient to make residue identification and quantification possible. Eggs and milk must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in eggs, milk, muscle, fat, kidney (except poultry), liver, and poultry skin. Representative samples from both of the studies must be analyzed using a suitable confirmatory method such as MS or HPLC. In addition, representative samples from these studies must be analyzed using a currently accepted or proposed enforcement analytical method in order to ascertain that the method is capable of adequately recovering and identifying all residues of concern. If the ruminant and/or poultry metabolism differs significantly from the rat data, then swine metabolism data will also be required.

Petitioner's Response

The petitioner did not respond.

CBTS Comments

CBTS reiterates that the nature of the pendimethalin residue in poultry is not adequately understood. CBTS reiterates that a poultry metabolism study using ring-labeled ¹⁴C-pendimethalin is necessary. The petitioner should identify at least 90 percent of the radiolabeled material in any new poultry metabolism study. The petitioner's report should include the % of the total radioactive residue (TRR) for each poultry part and the ppm value for the total TRR as well as each identified component of the TRR. Current Branch policy as outlined and explained in Attachment 3 to the "Overview of Residue Chemistry Guidelines" clearly states that CBTS now requires a poultry metabolism study whenever a pesticide is to be applied to a crop having a poultry feed commodity listed in Table II of the Residue Chemistry Guidelines. For safflower the poultry feed items listed in Table II are seed and meal. Safflower seeds can be 5 to 10 percent of broilers and laying hens diets. Safflower seed meal can be 10 percent of broiler diets and 5 percent of laying hens diets. Thus, a poultry metabolism study is necessary. The CBTS "Overview of Residue Chemistry Guidelines" by R.D. Schmitt,

Ph.D., Chief, with attachments is included with this review. CBTS reiterates that the above deficiencies remain unresolved and continue outstanding.

In a related co-pending petition (PP# 3F 2788) the petitioner presented the results of a caprine metabolism study using ^{13}C - and ^{14}C -ring labeled pendimethalin. Measurable or detectable residues were found only in caprine liver ranging from 0.08 ppm to 0.17 ppm from a 6.5 ppm dose. Trace amounts were also found in caprine kidney (about 0.02 ppm) and in caprine milk <0.01 ppm. Fractionating of various liver extracts revealed numerous free, unbound ^{14}C -components in the 0.005ppm to 0.025 ppm range which were not characterized. CB suggests the petitioner repeat the HPLC identification step for all fractions containing 0.005 pm and above, characterizing the major peaks using detectors that can elucidate organic structure such as but not limited to MS, FTIR, FTUV, NMR, etc. This information is essential for CB to ascertain the need for a ruminant feeding study. The petitioner needs to confirm the presence of or absence of all metabolites identified in the rat metabolism study. If the ruminant metabolism study differs significantly from the rat metabolism study, then a ^{14}C -ring labeled pendimethalin porcine metabolism study is necessary.

CBTS reiterates the above deficiencies. They remain unresolved and continue outstanding.

RESIDUE ANALYTICAL METHOD

Deficiencies

The following additional method is required:

- o A validated confirmatory method (MS is recommended) for residues of pendimethalin per se and its metabolite (CL 202,347).
- o Representative samples of plant and animal tissues containing residues of pendimethalin and its 3,5-dinitro-benzyl alcohol metabolite must be analyzed by multiresidue Protocols C and E and PAM Vol. I, Appendix II.
- o If radiolabeled validation of existing analytical methodology for plants and animals (refer to "Qualitative Nature of the Residue" and "Qualitative Nature of the Residue in Animals" for additional details) indicates a major portion of the total radioactive residue is not recovered by these methods, radiolabeled validation of new proposed analytical methodology will be required.

Petitioner's Response

The petitioner did not respond.

CBTS Comments

CBTS reiterates the above deficiency. It continues unresolved and remains outstanding.

After reconsideration of the requirements for MRM testing CB now concludes that additional MRM validation data are necessary for FDA MRM's A thru E. Chromatographic data are required for pendimethalin and its alcohol metabolite for Protocol C. Representative samples of plant and animal tissues need to be analyzed by appropriate MRM Protocol B, D, and E following the FDA decision tree for MRM testing. The protocols are found in FDA's PAM-I, Appendix II. This part of the deficiency is not resolved and continues outstanding.

STORAGE STABILITY DATADeficiencies

The following additional data are required for this petition:

- o Data reflecting the stability of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (CL 202,347) in or on representative plant [such as root and tuber vegetables, legume vegetables, cereal grains, and miscellaneous crops (cottonseed, peanuts, and sunflower seed)] and animal samples stored at freezing temperatures for time intervals approximating those of the treated samples used to determine the magnitude of the residue.

- o The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for plant commodities (raw and processed foods and feeds). Storage stability data in support of previously submitted residue data are required for only those samples deemed to be useful for tolerance assessment. The purity of the reference standards used for fortification of samples, and a complete description of the analytical methods (including extraction procedures) and method validation data used to supply the data in MRID 40535101 must be provided. For additional guidance on conducting storage stability studies, the registrant is referred to an August, 1987 Position Document on the Effects of Storage Validity of Pesticide Residue Data available from NTIS under order no PB 88112362/AS.

Petitioner's Response

The petitioner did not respond.

CBTS Comments

CBTS reiterates the above deficiency. It continues unresolved and remains outstanding.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALSCBTS Comments

The petitioner has previously submitted safflower and sunflower pendimethalin residue data. From the proposed use rate of 1.5 lbs a.i./ acre/ application and from exaggerated application rate of 2 lbs a.i. (1.3X) on trials in California and Montana no residues of either parent or the dinitrobenzyl alcohol were detected in the safflower seeds to the limit of detection, <0.05 ppm. Likewise no residues of pendimethalin and its metabolite were detected in sunflower seeds to the limit of detection, <0.05 ppm (see PP#0F2373).

CBTS reiterates there are adequate crop field trial residue data to show that when Prowl® Herbicide is used as directed residues of pendimethalin and its alcohol metabolite are not expected to exceed the proposed tolerance.

MAGNITUDE OF THE RESIDUE - MEAT/MILK/POULTRY/EGGSDeficiencies

The following data are required:

- o Lactating ruminants must be dosed with 0.1, 0.3, and 1.0 ppm pendimethalin per se (\geq three animals/dose group) in the total diet until residues plateau in milk or for 28 consecutive days if no residues are detected in milk. Milk samples must be obtained twice daily. Animals must be sacrificed within 24 hours of the final dose and residues in tissues (muscle, liver, kidney, and fat) determined.

- o Poultry must be dosed with 0.1, 0.3, and 1.0 ppm pendimethalin per se (\geq 10 hens/dose group) in the total diet. Egg samples should be collected twice daily and analyzed for residues; dosing should continue until residues in eggs plateau or for 28 days if residues are nondetectable. Hens should be sacrificed within 24 hours of the final dose and residues determined in muscle, fat, kidney, and liver, and other edible tissues.

- o Since the residues of concern in animal products have not been delineated, at the present time we require data reflecting residues of pendimethalin per se and its metabolite CL-202,347. Other residues may need to be sought if requested metabolism studies so indicate.

o The available goat metabolism study (see Nature of the Residue in Animals) indicates that residues of pendimethalin may occur in meat and meat by-products of food animals. Tolerances must be proposed for these food commodities, if the above-required data so indicate.

Petitioner's Response

The petitioner did not respond.

CBTS Comments

CBTS reiterates the above deficiencies. They continue unresolved and remain outstanding.

CBTS points out that, in the "Overview of the Residue Chemistry Guideline," current Branch policy is that animals should be kept on the treated feed for 4 weeks. However, if residues have not plateaued in eggs or milk by the end of 4 weeks, then the feeding period should continue until a plateau is reached.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

CBTS Comments

The petitioner has previously submitted a safflower processing study. In that study, safflower seeds containing no detectable residues were processed into meal, oil, hulls, and soapstock in which no detectable residues were found. Upon further consideration, CBTS now concludes that this safflower processing study is not adequate and should be repeated as described below.

Based on the requirements as stated in the Residue Chemistry Guidelines, the petitioner needs to conduct additional crop field trials at the proposed pendimethalin use rate and/or highest practical pendimethalin application rate. If detectable residues are found in the raw safflower seed, then a processing study is necessary; and if the data show a concentration of residues, then a food additive tolerance is required. Residue data are necessary for safflower meal, crude safflower oil, and refined safflower oil.

If exaggerated rate data are available and there are detectable residues, then these samples should be used for a processing study. If residues concentrate on processing, then the concentration factor should be applied to the raw agricultural commodity (RAC) tolerance to arrive at a food/feed additive tolerance (FAT).

If pendimethalin exaggerated rate data are available and there are no detectable residues in the RAC safflower seed, then no FAT is required provided that:

1. The application rate is exaggerated by at least the theoretical concentration factor.
2. The crop field trial data are sufficiently representative of the major safflower seed growing regions so that any reasonable potential for detectable residues has been realized.
3. The exaggerated rate was not unrealistically high. The level of exaggerated application acceptable will depend on the use.

If application of the highest practical exaggerated pendimethalin rate results in no detectable residues and the level of exaggeration is less than the theoretical concentration factor, then these safflower seeds are to be processed. If no detectable residues are found in the processed safflower meal, crude and refined oil, then no FAT is required. If any of the processed commodities contain any pendimethalin and its metabolite residues, a FAT is required. In cases where the raw, safflower seeds contain no detectable pendimethalin residues, the processing study will indicate only that the minimum concentration factor is the ratio of the concentration in the processed commodity to the limit of detection (not quantification) in the RAC. CBTS will evaluate all available data in determining what is the appropriate concentration factor. This will include, at a minimum, the metabolism studies and chromatographic support data for the RAC. In some cases it may be possible to estimate residue levels from chromatograms where the response is below the limit of reliable quantification but nonetheless indicative of a "true" residue.

Attachment: Overview of Chemistry Guidelines

H7509C:CBTS:Reviewer(FDG):CM#2:Rm814B:557-0826:557-0826:JOB:
64799:I:C.Disk:KEVRIC:01/30/91:tlc:WO:DD:CL:wo:aw:ed:fdg:2/5/91.

cc:R.F., Circ(7), Reviewer(FDG), PP#3F2844, Pendimethalin Reg Std
File, PIB/FOD (Furlow).

RDI:SecHd:RSQuick:2/25/91:BrSrSc:RALoranger:2/26/91.