for MRID 41469701

PMSD/ISB

CONFIDENTIAL

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

MAR 19 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Pendimethalin Product Chemistry and Residue Chemistry Registration Standard Update.

FROM: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch (DEB)
Health Effects Division (H7509C)

Richard D Schmitt

TO: Lois Rossi, Chief
Reregistration Branch
Special Review & Reregistration Division (H7508C)

and

Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Attached are updates to the Product and Residue Chemistry Chapters of the Pendimethalin Reregistration Standard prepared by Dynamac Corporation under supervision of the Dietary Exposure Branch, HED. They have undergone secondary review in the Dietary Exposure Branch and have been revised to reflect the Branch policies. The original Guidance Document was issued in March 1985.

These documents provide an in-depth analysis of the status of the Pendimethalin Product and Residue Chemistry data bases as of 12/4/89. Revised data requirement tables are included.

Please note that Confidential Business Information accompanies the Product Chemistry Update as Confidential Appendices A, B and C.

If you need additional input please advise.

Attachment 1: Pendimethalin Product Chemistry Reregistration Standard Update

Attachment 2: Confidential Appendices A, B and C.

Attachment 3: Pendimethalin Residue Chemistry Reregistration Standard Update

cc (with attachments 1, 2 & 3): E. Haeberer, L. Rossi (RB, SRRD), R. Engler (SACB, HED), Pendimethalin Reregistration Standard file, Pendimethalin Subject File, J. Burrell (FOD)

cc (without attachments): W. Boodee, RF, Circ.(8), M. Hawkins (HED), P. Fenner-Crisp (HED)

DYNAMAC
CORPORATION

Final Report

PENDIMETHALIN
Task 4: Residue Chemistry
Registration Standard Update

February 28, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
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PENDIMETHALIN

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INTRODUCTION

The 5/2/89 update of the Index of Pesticide Chemicals identifies registered food/feed uses for the herbicide pendimethalin on the following crops: alfalfa, beans (succulent and dry), corn (field and sweet), cotton, peanuts, potato, rice (dry seeded), sorghum (grain crop), soybeans, and sunflower. Pendimethalin is also registered for use on the following nonbearing orchard crops: almond, apple, apricot, cherry, citrus, English walnut, grape, nectarine, peach, pistachio, and plum (fresh prunes). The Index also identifies pendimethalin as registered for use on tobacco (burley and flue-cured, and transplants). Pendimethalin formulations registered for preplant incorporation, preemergence, at-planting, early postemergence and postemergence applications to food/feed crops (except alfalfa) include the 1, 2.8, 3, and 4 lb/gal emulsifiable concentrate (EC), the 60% dry flowable (DF), and the 40% soluble concentrate/liquid (SC/L). The EC formulations may contain multiple active ingredients. The 4 lb/gal EC formulation is also registered for: (i) application to dormant alfalfa grown solely for seed production; (ii) soil directed application to nonbearing orchard crops; and (iii) layby application to tobacco transplants.

The Pendimethalin Guidance Document dated March 29, 1985 identifies residue chemistry data gaps for plant metabolism, animal metabolism, residue analytical methods, storage stability, and magnitude of the residue in soybean forage, soybean hay, and the processed products of corn, cottonseed, peanuts, sorghum, soybeans, and sunflower. Residue chemistry data are also required for the magnitude of the residue in fish and tobacco. In response to these requirements, American Cyanamid Company has submitted data pertaining to storage stability (1987; MRID 40063201; and 1988; MRID 40535101), corn grain (1986; MRID 40185102), and soybean foliage (1986; MRIDs 00161759, 00161760, 00161761, and 40185101). The available data, up to December 4, 1989, have been reviewed by the Agency or are otherwise reviewed here for their adequacy in fulfilling the outstanding data requirements.

Since issuance of the 1985 Pendimethalin Guidance Document, tolerances for residues of pendimethalin and its 5-dinitrobenzyl alcohol metabolite in or on beans (succulent and dry), bean forage, bean hay, and sweet corn (K+CWHR) have been established. Data submitted in support of these tolerances have undergone

Agency review (refer to petition files PP#1F2567 and PP#2F2628 for Agency reviews on beans and corn, respectively).

Tolerances for the residues of pendimethalin in or on raw agricultural commodities are currently expressed in terms of the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite [40 CFR §180.361(a) and (c)]; except for peanut hulls. The tolerance for residues in or on peanut hulls is currently expressed in terms of combined residues of pendimethalin, its 3,5-dinitrobenzyl alcohol metabolite, and its 2,4-dinitrobenzyl alcohol metabolite [40 CFR §180.361(b)].

SUMMARY

The following Pendimethalin Residue Chemistry data are required:

- Additional data pertaining to the qualitative nature of the residue in plants.

- Additional data pertaining to the qualitative nature of the residue in ruminants and poultry.

- Representative samples of plant and animal tissues containing residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite must be analyzed by multiresidue Protocols C and E from PAM Vol. I, Appendix II.

- 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) used to support tolerances.

- The registrant must provide a description of the analytical method and provide recovery data to validate the submitted residue data on soybean foliage.

- A processing study depicting pendimethalin residues of concern in wet milled products (starch, crude oil, and refined oil) and in dry milled products (grits, meal, flour, and crude and refined oils) processed from field corn bearing measurable, weathered residues is required to depict the concentration of residues in the oil of oil seeds (cottonseed, peanuts, soybeans, and sunflowers). The registrant should complete the required plant metabolism data before submitting data from a processing study.

- Processing studies depicting pendimethalin residues of concern in items processed from rice grain and sorghum grain bearing measurable, weathered residues.

- o Studies must be conducted using grapes and representative fruit and nut trees in which [^{14}C]pendimethalin is applied to the base of trees just prior to flowering at an exaggerated rate. If measurable ^{14}C-residues occur in mature fruit, the identities and quantities of all such residues must be determined.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The Pendimethalin Guidance Document dated March 29, 1985 concludes that the qualitative nature of the residue in plants is not adequately delineated and requires additional data to reveal the complete identity of the total radioactive residue. American Cyanamid Company (letter dated 6/28/85) responded to these data requirements by asserting that the available data demonstrate that essentially no pendimethalin is taken up by plants and that the level of radioactive residues in samples from the existing plant metabolism studies is too low to allow characterization of metabolites; thus, they concluded that additional plant metabolism data are unnecessary. The Agency, in turn, reiterated the need for additional plant metabolism data, recommending more rigorous hydrolysis steps to release unextractable residues and stating the need for characterization of these residues or demonstrating unequivocally that unextractable radioactivity is incorporated into natural plant products (R.J. Taylor in a letter to American Cyanamid dated 4/16/86). American Cyanamid, in a letter dated 5/14/86, restated their argument against the need for additional data on plant metabolism. The Agency (R. Taylor in a letter dated 5/10/89) upheld the requirements for data on plant metabolism. Therefore, the requirement for additional plant metabolism data remains outstanding for the reasons and with the recommendations stated previously by the Agency (letters by R. Taylor dated 4/16/86 and 5/10/89). The following additional data are required:

- O Data depicting the distribution and metabolism of [^{14}C]pendimethalin in or on mature plant parts from three dissimilar food crops (e.g., a root crop, oilseed crop, and a leafy vegetable). If metabolism is not similar in the three crops, additional studies using other crops may be required. A completely characterized test substance representative of technical pendimethalin (including impurities, if appropriate) used in commercial formulations must be applied at levels sufficiently high to permit characterization of ^{14}C-residues. The identities and quantities of extractable and nonextractable residues must be determined. Confirmation of the identities of residues using a suitable

confirmatory method such as MS or HPLC is also required. In addition, representative samples from the tests must be analyzed using a currently accepted or proposed enforcement analytical method in order to ascertain that this method will determine all possible metabolites of concern.

Although incomplete, the available metabolism data do indicate that pendimethalin [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] residues are adsorbed and translocated by plants. Assessment of the adequacy of the current tolerance expression cannot be made until the required plant metabolism data have been received and evaluated.

References (used):

MRID(s): N/A.

Discussion of the data:

N/A.

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The Pendimethalin Guidance Document dated March 29, 1985 concludes that the qualitative nature of the residue in animals is not adequately delineated and requires additional data on the metabolism of [^{14}C]pendimethalin in ruminants. American Cyanamid Co. (letters dated 6/28/85 and 5/14/86) responded to the Guidance Document data requirements by contending that the previously submitted animal metabolism data demonstrate that no residues will occur in meat or milk as a result of livestock ingesting treated forage commodities. The Agency has informed American Cyanamid (letters by R.J. Taylor dated 4/16/86 and 5/10/89) that the requirement for additional animal metabolism data remains outstanding. The registrant has stated the intention to carry out a study of ruminant metabolism.

Metabolism data for poultry were not required in the Guidance Document because poultry feed items did not contain any detectable residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite. However, current guidelines require additional data on the metabolism of [^{14}C]pendimethalin in poultry.

No data have been submitted in response to the Guidance Document; therefore, data requirements for this topic are still outstanding. The following additional data are required:

- Metabolism studies utilizing ruminants and poultry. Animals must be dosed orally with ring-labeled [^{14}C]-pendimethalin for a minimum of three 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.

Although the metabolism of pendimethalin in animals has not been adequately characterized and identified, the following compounds have been identified in the tissues and urine of rats: pendimethalin, its 3,5-dinitrobenzyl alcohol metabolite (4-[(1-ethylpropyl)-amino]-2-methyl-3,5-dinitrobenzyl alcohol), 4-[(1-ethylpropyl)-amino]-3,5-dinitro-o-toluic acid, 3-(2,6-dinitro-3,4-xylidino-2-pentanol, 4-[[(1-carboxymethyl)propyl]amino]-3,5-dinitro-o-toluic acid, and 4-[(1-ethyl-2-hydroxypropyl)amino]-3,5-dinitro-o-toluic acid. Two additional metabolites, 4-amino-3,5-dinitro-o-toluic acid and 4-[(1-ethyl-3-hydroxypropyl)amino]-3,5-dinitro-o-toluic acid have also been identified in rat urine, but not in rat tissues. In addition, pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite have been identified in goat urine and fish tissues.

References (used):

MRID(s): N/A.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Conclusions:

The qualitative nature of the residue in plants and animals has not been adequately described. The Pendimethalin Guidance

Document dated March 29, 1985 reserves the requirement for additional analytical methods for data collection and enforcement pending submission and evaluation of the requested data regarding the nature of the residue in plants and animals. No plant or animal metabolism data have been submitted in response to the Guidance Document; therefore, the adequacy of the available analytical methods cannot be ascertained. Also, for all food uses, data on whether the FDA multiresidue methodology would detect and identify a pesticide are required (40 CFR 158.240). The FDA Pestrack database (PAM Vol. I Appendix dated 10/25/89) contains data concerning the applicability of multiresidue methods to pendimethalin per se (Protocol D; nonfatty foods). No data are available for the 3,5-dinitrobenzyl alcohol metabolite. The following additional data are required:

- Representative samples of plant and animal tissues containing residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite must be analyzed by multiresidue Protocols C and E from PAM Vol. I, Appendix II.

- If radiolabeled validation of existing analytical methodology for plants and animals (refer to "Qualitative Nature of the Residue in Plants" and "Qualitative Nature of the Residue in Animals" for additional details) indicates a major portion of the total radioactive residue is not recovered and identified by these methods, radiolabeled validation of new proposed analytical methodology will be required.

The currently preferred enforcement methods include: (i) GLC methods using Florisil cleanup and electron capture detection for determination of residues of pendimethalin per se in soybeans (dry and green seeds, meal, plants, and oil) and in cotton (plants, seed, seed meal, and oil), published in PAM Vol. II, Methods I and III, respectively; and (ii) GLC methods using Florisil cleanup and electron capture detection for determination of residues of the 3,5-dinitrobenzyl alcohol metabolite (4-[(1-ethylpropyl)-amino]-2-methyl-3,5-dinitrobenzyl alcohol) in soybeans (dry and green seeds, meal, plants, and oil) and in cotton (plants, seed, seed meal, and oil), published in PAM Vol. II, Methods II and IV, respectively.

References (used):

MRID(s): N/A.

Discussion of the data:

N/A.

STORAGE STABILITY DATA

Conclusions:

The Pendimethalin Guidance Document dated March 29, 1985 concludes that additional data are required to show the stability of residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite in or on representative plant and animal samples stored at freezing temperatures for time intervals approximating those of the treated samples used to determine the magnitude of the residue.

In response to requirements for storage stability data, American Cyanamid Company (1985; MRID 40535101) submitted data depicting the stability of pendimethalin per se and its 3,5-dinitrobenzyl alcohol metabolite in plant commodities stored at subfreezing temperatures for up to ca. 2 years. These data do not satisfy requirements for the topic because the sample storage conditions and intervals for all residue data used to support established tolerances were not provided. Furthermore, the purity of the reference standards used for fortification of samples was not given, and a complete description of the analytical methods (including extraction procedures) and method validation data, although referenced, was not included in this submission. The recently submitted data do indicate that residue decline of both pendimethalin per se and its 3,5-dinitrobenzyl alcohol metabolite in plant commodities under the tested conditions and intervals appears to be limited; however, variability in recovery between storage intervals impairs calculation of a useful correction factor. The following additional data are required:

- 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.

- The nature of the residue in plants and animals is not adequately understood. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting the stability of those residues during storage will be required.

References (used):

MRID(s): 40535101.

References (not used):

[The following reference(s) contains data duplicated in MRID 40535101.]

MRID(s): 40063201.

Discussion of the data:

American Cyanamid Company (1985; MRID 40535101, Report No. C-2695.2) submitted data from a test pertaining to storage stability of residues of pendimethalin per se and its 3,5-dinitrobenzyl alcohol metabolite in or on almonds (hulls and kernels), grapes and raisins, onion bulbs, potatoes, soybeans (seeds and plants), tobacco, and wheat straw. Commodities were fortified with both pendimethalin per se and its 3,5-dinitrobenzyl alcohol metabolite at 0.1 and 1.0 ppm, and maintained frozen at -9 to -23 C for up to 799 days (purity of the compounds was not reported). Residue analysis was accomplished using a GLC with nitrogen specific detection (refer to Table 1 for method designations); these methods were not fully described and validation data were referenced but not included in the current submission. The limit of detection was 0.05 ppm each for pendimethalin per se and its 3,5-dinitrobenzyl alcohol metabolite. Recoveries of initial fortification levels at various storage intervals are detailed in Table 1.

Table 1. Stability of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (DNBA) in various commodities fortified at 0.1 and 1.0 ppm and stored frozen for various intervals.

Commodity	Residue Analytical Method	Storage Interval (days)	Recovery (%) pendimethalin fort. (ppm) 0.1	pendimethalin fort. (ppm) 1.0	3,5 DNBA fort. (ppm) 0.1	3,5 DNBA fort. (ppm) 1.0
Almond hulls	M-1473/M-1472[a]	13	113	102	57	71
		91	102	83	71	88
		185	94	91	41	63
		366	--[b]	94	--	108
Almond kernels	M-1467/M-1474	13	108	100	104	100
		91	86	79	67	--
		185	98	100	70	83
		366	106	83	92	86
Grapes	M-1404/M-1405	0	95	81	--	--
		30	88	75	59	69
		105	85	74	45	51
	M-1622/M-1623	176	96	83	86	86
		434	102	90	92	89
		560	69	81	90	87
		793	88	108	82	103
Raisins	M-1404/M-1448	0	91	81	69	--
		30	88	77	31	62
		105	104	92	44	63
	M-1622/M-1623	176	96	83	86	74
		365	83	57	63	77
		557	89	99	69	95
		791	75	91	120	104
Onion bulbs	M-1502/M-1503	0	111	80	--	--
		32	70	--	87	95
		95	111	86	103	90
		187	103	102	37	30
		365	108	87	--	--
	M-1737/M-1737	579	89	84	112	88
		799	88	80	88	68
Potato tubers	M-1493/M-1313	20	131	89	87	88
		91	125	95	66	79
		197	137	104	61	97
		385	107	100	70	145

(Continued, footnotes follow)

TABLE 1. (Continued).

Commodity	Residue Analytical Method	Storage Interval (days)	Recovery (%) pendimethalin fort. (ppm) 0.1	pendimethalin fort. (ppm) 1.0	3,5 DNBA[a] fort. (ppm) 0.1	3,5 DNBA[a] fort. (ppm) 1.0
Soybean plants	M-1609/M-1609	0	95	93	126	109
		30	98	105	113	88
		90	100	87	70	89
		181	109	86	--	79
		349	97	87	89	104
		685	69	76	90	97
Soybean seeds	M-1602	0	109	93	--	--
		30	88	97	--	--
	M-1625/M-1625	127	96	80	50	82
		149	85	71	76	81
		365	49	48	91	70
		546	53	53	99	98
Tobacco	M-1440/M-1440	0	87	73	--	--
		30	94	72	--	--
		91	90	69	--	--
		182	100	76	--	--
		365	88	78	--	--
		573	78	74	--	--
		768	100	80	--	--
Wheat straw	M-1624/M-1624	0	104	106	114	114
		30	98	95	77	80
		92	98	92	100	88
		183	104	87	--	109
		370	78	84	75	103
		546	84	95	93	88
		736	93	107	128	127

[a] The methods for detection of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite are listed respectively for the specific storage interval listed, and for successive intervals, up to the next listed method(s). Two methods are listed as improved methods (M-1622 and M-1623), and another is listed as a new method (M-1625).

[b] Signifies no data were submitted for these storage intervals.

In summary, these data indicate that residue decline of both pendimethalin per se and its 3,5-dinitrobenzyl alcohol metabolite in plant commodities under the tested conditions and intervals appears to be limited; however, variability in recovery between storage intervals impairs calculation of a useful correction factor. Additional data are required: 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.

MAGNITUDE OF THE RESIDUE IN PLANTS

The Pendimethalin Guidance Document dated March 29, 1985 identifies field residue data requirements for soybean forage, soybean hay, and tobacco. Also, processing studies are required for oil seed crops: corn grain, cottonseed, peanuts, rice grain, sorghum grain, soybeans, and sunflower seeds. American Cyanamid Company responded to these requirements in a letter dated 6/28/85 arguing that a potential for residue concentration in oil (25x based on the percent oil in the grain) to a level exceeding the established tolerance for residues in or on the grain (0.1 ppm) exists only for corn. They also contend that residues in or on corn grain at or near the tolerance cannot be obtained from less than phytotoxic treatment levels. The Agency (R. Taylor in a letter dated 5/10/89) informed American Cyanamid that a processing study, using corn instead of soybeans as specified in the Guidance Document, would fulfill the requirements for data depicting the concentration of residues in the oil of oil seeds. It was added that these data should be submitted after the required plant metabolism studies are complete. With the exception of soybean foliage and corn grain, no data have been submitted in response to these requirements.

Outstanding data gaps for use of pendimethalin in nonbearing vineyards and fruit and nut tree orchards and for processing studies on rice grain and sorghum grain reflect recent changes in Agency policy regarding requirements for residue chemistry data.

Note to SRRD: The data gaps which appear in this update are based on the assumption that the use patterns for pendimethalin have not changed since publication of the Guidance Document.

The conclusions stated in this section regarding the adequacy of established tolerances may change on receipt of required plant metabolism data. The registrant should be urged to complete and submit all required plant metabolism studies prior to initiation of required field trials and processing studies.

Foliage of Legume Vegetables Group

Soybean forage and hay

Tolerance(s):

A tolerance of 0.1 ppm has been established for the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite in or on soybean forage [40 CFR §180.361(a)].

Use directions and limitations:

The 4 lb/gal EC and the 60% DF formulations are registered for use on soybeans (excluding CA) at 0.5-2 lb ai/A. A single preplant broadcast or band application (aerially or ground-applied) is incorporated within 7 days of application. The 4 lb/gal EC and 60% DG formulations are all registered for preemergence application to no-till soybeans (at-planting or 2 days after planting) at 0.5-1.25 lb ai/A. The formulations may be applied using aerial or ground equipment and may be tank-mixed with other herbicides.

Since publication of the Pendimethalin Registration Standard, a 2.8 lb/gal EC formulation (EPA Reg. No. 241-315) has been registered for use on soybeans. However, the data gaps which appear in this update are based on the assumption that the use patterns for pendimethalin have not changed since publication of the Guidance Document.

Conclusions:

The Pendimethalin Guidance Document dated March 29, 1985 requires additional data depicting residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite in or on soybean hay and straw resulting from at-planting ground or aerial application of the 4 lb/gal EC formulation or the 60% dispersible granule (DG) formulation (currently registered as the 60% dry flowable (DF)) at 2 lb ai/A. These tests must be conducted in Illinois, Minnesota and Missouri.

Data on soybean foliage (1987; MRID 40185101) were submitted in response to this requirement, and were the subject of an Agency review (D. Edwards, EPA Memorandum DEB No. 5495, dated 9/8/89). These data indicate that combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite are not likely to exceed the established tolerance of 0.1 ppm in or on soybean hay or straw following registered use. However, recovery data for the analytical method (M-1609), referenced as being available in Report No. C-2667, could not be located in the submission. Therefore, the registrant needs to submit these validation data.

Additional data on soybean foliage (1986; MRIDs 00161759, 00161760, and 00161761) were submitted in response to the Guidance Document. These data (from IL, MN, and MO) indicated similar results as detailed above for MRID 40185101; i.e. the registrant needs to submit validation data for the analytical method (M-1609). Therefore, the following additional data are required:

- The registrant must provide a description of the analytical method and provide recovery data to validate the submitted residue data on soybean foliage.

References (used):

MRID(s): 00161759. 00161760. 00161761.

References (not used):

[The following reference(s) is a supplement to MRID 40185101, and contains only a corrected typographical error.]

MRID(s): 40260601

Discussion of the data:

American Cyanamid Company submitted data from three tests conducted in IL, MN, and MO (1986; MRIDs 00161759, 00161760, and 00161761, respectively) depicting combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite in or on soybean hay or straw (only hay in MN) harvested 52 or 60 days after an at-planting ground application of the 4 lb/gal EC formulation at 2 lb ai/A. Combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite were <0.1 ppm (nondetectable, including <0.05 ppm of each compound) in or on each of two samples of straw and three samples of hay. Control samples also bore nondetectable residues. All samples were stored frozen (-18 C) for about 6 months until analysis by GLC (Method M-1609); the method was not described. The limit of detection was reported as 0.05 ppm. Recovery data were not presented. These data indicate that the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite are not likely to exceed the established tolerance of 0.1 ppm in or on soybean hay or straw following registered use. We note that although validation data for the analytical method (M-1609) were referenced as being available in Report No. C-2667, these data could not be located in this submission. The registrant needs to submit these validation data.

Cereal Grains Group

Corn Grain

Tolerance(s):

A tolerance of 0.1 ppm has been established for the combined residues of pendimethalin and its 3,5-dintrobenzyl alcohol metabolite in or on corn grain [40 CFR §180.361(a)].

Conclusions:

The Pendimethalin Guidance Document dated March 29, 1985 stated that the need for processing data would be determined following receipt of the requested plant metabolism data and that when necessary, data from a soybean processing study could be extrapolated to the other oil-seed crops. Seeking a waiver for the requirements of an oil-seed processing study, American Cyanamid Company submitted data (1987; MRID 40185102) depicting residues of pendimethalin per se in or on corn grain harvested 118-187 days following preemergence or postemergence application of the 4 lb/gal EC formulation at 1.5-4 lb ai/A (0.75-2x the maximum registered rate). These data were the subject of an Agency review by D. Edwards (EPA Memorandum DEB No. 5495, dated 9/8/89) who concludes that the submitted data cannot be used to fulfill the requirement for an oil-seed processing study because no data were reported on the 3,5-dinitrobenzyl alcohol metabolite of pendimethalin which is included in the tolerance definition. Moreover, the nature of the residue in plants is not adequately understood and the potential for concentration of additional metabolites may have to be considered. It should be noted that the registrant's argument for waiving the requirement for a processing study is based on the very low limit of detection of the analytical method used in the submitted residue study; however, data validating the method cannot be located. The requirement for an oil-seed processing study remains outstanding. Therefore, the following additional data are required:

- A processing study depicting pendimethalin residues of concern in wet milled products (starch, crude oil, and refined oil) and in dry milled products (grits, meal, flour, and crude and refined oils) processed from field corn bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed. These data will fulfill the requirements for data depicting the concentration of residues in the oil of oil seeds (cottonseed, peanuts, soybeans, and sunflowers). The registrant should complete the required plant metabolism data before submitting data from a processing study.

References (used):

N/A.

Discussion of the data:

N/A.

Nonbearing Orchard Crops

Tolerance(s):

No tolerances exist at the present time for the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite in or on almonds, apples, apricots, cherries, citrus, English walnuts, grapes, nectarines, peaches, pistachios, and plums (fresh prunes).

Use directions and limitations:

The 4 lb/gal EC formulation may be applied as a soil-directed application in nonbearing fruit and nut orchards (almonds, apples, apricots, cherries, citrus, English walnuts, nectarines, peaches, pistachios, and plums (fresh prunes) and vineyards at 4 lb ai/A. Livestock may not graze or be fed forage in treated areas. These use directions were obtained from the product label (EPA Reg. No. 241-243, dated 4/15/86).

Conclusions:

The appropriate classification of the registered nonbearing use of pendimethalin in vineyards and fruit and nut orchards as a "food" or "nonfood" use has not been determined. The following additional data are required:

- Studies must be conducted using grapes and representative fruit and nut trees in which [^{14}C]pendimethalin is applied to the base of trees just prior to flowering at an exaggerated rate. If measurable ^{14}C-residues occur in mature fruit, the identities and quantities of all such residues must be determined.

MAGNITUDE OF THE RESIDUE IN MEAT, MILK, POULTRY AND EGGS

Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep

Conclusions:

The Pendimethalin Guidance Document dated March 29, 1985 requires data depicting residues in ruminant tissues and milk. No data

have been submitted in response to these requirements. Presently, data gaps exist concerning the magnitude of pendimethalin residues in soybean hay and straw and processed products of corn, cottonseed, peanuts, soybeans, and sunflower seeds. Upon receipt of the requested animal metabolism, method validation, field trial, and processing data, the expected dietary intake for beef cattle, dairy cattle, and swine will be calculated, and the need for additional feeding studies will be reevaluated.

References (used):

MRID(s): N/A.

Discussion of the data:

N/A.

Eggs and the Fat, Meat, and Meat Byproducts of Poultry

Conclusions:

The Pendimethalin Guidance Document dated March 29, 1985 reserves the requirement for additional data regarding the magnitude of residues in eggs, and the fat, meat, and meat byproducts of poultry pending submission and evaluation of the requested data regarding the nature of the residue in poultry. Presently, data gaps exist concerning the magnitude of pendimethalin residues in soybean hay and straw and processed products of corn, cottonseed, peanuts, soybeans, and sunflower seeds. Upon receipt of the requested animal metabolism, method validation, field trial, and processing data, the expected dietary intake for poultry will be calculated, and the need for additional feeding studies will be reevaluated.

MASTER RECORD IDENTIFICATION NUMBERS

Residue Chemistry Citations (used):

00161759 Tondreau, R.; Gingher, B. (1986) Prowl Herbicide...: Residues of CL 92,553 and CL 202,347 in Soybean Plants: Project No. 0463: Report No. C-2676. Unpublished study prepared by American Cyanamid Co. 11 p.

00161760 Tondreau, R.; Gingher, B. (1986) Prowl Herbicide...: Residues of CL 92,553 and CL 202, 347 in Soybean Plants: Project No. 0463: Report No. C-2677. Unpublished study prepared by American Cyanamid Co. 10 p.

00161761 Tondreau, R.; Gingher, B. (1986) Prowl Herbicide...: Residues of CL 92,553 and CL 202,347 in Soybean Plants: Project No. 0463: Report No. C-2675. Unpublished study prepared by American Cyanamid Co. 13 p.

40185101 Tondreau, R.; Gingher, B. (1987) Soybean Residue Studies with Prowl (R) Herbicide in Illinois and Minnesota: Lab. Rept. No. CY2. Unpublished compilation prepared by American Cyanamid Co. 37 p.

40185102 Elenewski, C.; Gingher, B. (1987) Corn Residue Studies with Prowl (R) Herbicide in Iowa, Illinois, Ohio, Wisconsin, and Nebraska: Lab. Rept. No. CY3. Unpublished compilation prepared by American Cyanamid Co. 263 p.

40535101 Tondreau, R. (1988) Pendimethalin (C 92,553): Summary of Ongoing Freezer Stability Studies on CL 92,553 and CL 202, 347 (Metabolite) Residues in Several Different Types of Commodities: Report No. C-2695.2. Unpublished study prepared by American Cyanamid Co. 59 p.

Residue Chemistry Citations (not used):

[The following MRIDs contain data that were either not submitted in response to the Guidance Document or contain data that are not useful in satisfying residue chemistry data requirements.]

00142809 American Cyanamid Co. (19??) [Residue Data of Prowl Herbicide]. Unpublished compilation. 71 p.

00143477 American Cyanamid Co. (1984) [Residue Data on PROWL Herbicide]. Un published compilation. 16 p.

00152232 American Cyanamid Co. (1985) [Residue Data & Updated Supplemental Prowl Herbicide Labels]. Unpublished compilation. 95 p.

00153179 American Cyanamid Co. (1985?) [Residue Data of Sunflower with Prowl Herbicide]. Unpublished compilation. 94 p.

00159810 Steller, W. (1986) Letter sent to R. Taylor dated May 14, 1986: Prowl herbicide, Registration standard for products containing pendimethalin, dated March 29, 1985: Dynamac Task 4. Prepared by American Cyanamid Co. 177 p.

40063201 Elenewski, C.; Tondreau, R. (1987) Prowl Herbicide, Pendimethalin (CL 92,553): Summary of Ongoing Freezer Stability Studies on CL 92,553 and CL 202,347 (Metabolite) Residues in Several Different Types of Commodities: Report No. C-2695.1. Unpublished study prepared by American Cyanamid Co. 48 p.

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40140801 Elenewski, C. (1984) Prowl Herbicide, Pendimethalin (CL 92,553): Validation of GC Method M-1493 for the Determination of CL 92, 553 Residues in Potato Tubers (Supersedes Method M-0615): Laboratory Report No. C-2484. Unpublished study prepared by American Cyanamid Co. 12 p.

40140802 Smith, J. (1983) Prowl Herbicide, Pendimethalin (CL 92,553): Validation of GC Method M-1313 for the Determination of CL 202,347 Residues in Potato Tubers (Supersedes Method M-0615): Laboratory Report No. C-2235. Unpublished study prepared by American Cyanamid Co. 14 p.

40260601 Tondreau, R.; Gingher, B. (1987) Supplement to Soybean Residue Studies with Prowl Herbicide in Illinois and Minnesota: Laboratory Report No. CY2. Unpublished study prepared by American Cyanamid Co. 3 p.

[The following MRIDs pertain to pending tolerances for residues on crops which do not have a currently registered use.]

00145203 American Cyanamid Co. (1983) Residues of Prowl Herbicide. Unpublished compilation. 148 p.

00150401 American Cyanamid Company (1984) Residue Chemistry: [Prowl Residues in Grapes and Raisins]. Unpublished compilation. 247 p.

40232501 Baron, J. (1987) Pendimethalin-Magnitude of Residue on Garlic: Lab Project ID: PR-2752. Unpublished study prepared by Univ. of Calif., Davis. 92 p.

40703401 Elenewski, C.; Smith, J.; Tondreau, R. (1987) Prowl Herbicide (AC 92,553/ 4EC): Residues of CL 92,553 and Cl202,347 in Almonds: Report Nos. C-2646; C-2654; C-2663; C-2695.1. Unpublished study prepared by American Cyanamid Co. 136 p.

2

TABLE A. GENERIC DATA REQUIREMENTS FOR PENDIMETHALIN.

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.240 Residue Chemistry				
171-2. Chemical Identity[3]				
171-3. Directions for Use	(See Index)[4]			
171-4. Nature of the Residue (Metabolism) - Plants	PAIRA	Partially		Yes[5]
171-4. Nature of the Residue (Metabolism) - Livestock	PAIRA & plant metabolites	Partially		Yes[6,7]
171-4. Residue Analytical Methods	TGAI & metabolites	Partially		Yes[8] Reserved[9]
171-4. Storage Stability	TEP & metabolites	Partially	40535101	Yes[10] Reserved[11]
171-4. Magnitude of Residue in Plants				
Root and Tuber Vegetables - Potatoes	TEP	Yes		No
Legume Vegetables - Beans (dry, succulent, & limas)	TEP	Yes		No

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
- Soybeans	TEP	Yes		No
(processed commodities)	TEP	No		Yes[13]
Foliage of Legume Vegetables				
- Bean vines & hay	TEP	Yes		No
- Soybeans forage & hay	TEP	Partially	00161759 00161760 00161761	Yes[12]
Cereal Grains				
- Corn (field & sweet)	TEP	Yes		No
(processed commodities)	TEP	No		Yes[13]
- Rice	TEP	Yes		No
(processed commodities)	TEP	No		Yes[14]
- Sorghum	TEP	Yes		No
(processed commodities)	TEP	No		Yes[15]
Forage, Fodder, and Straw of Cereal Grains				
- Corn forage & fodder	TEP	Yes		No
- Sorghum forage & fodder	TEP	Yes		No
Miscellaneous Commodities				
- Cottonseed	TEP	Yes		No
(processed commodities)	TEP	No		Yes[13]
- Peanuts	TEP	Yes		No
(processed commodities)	TEP	No		Yes[13]

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
- Peanuts forage & hay	TEP	Yes		No
- Sunflower seeds	TEP	Yes		No
(processed commodities)	TEP	No		Yes[13]
- Tobacco	PAIRA	Partially		Yes[16]
- Nonbearing Orchard Crops	PAIRA	No		Yes[17]
171-4. Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially		Reserved[18]
- Fish	TGAI or plant metabolites	N/A		No[19]

1. Test substance: PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = Typical end-use product; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

2. These references were submitted in response to the Pendimethalin Guidance Document dated 4/9/85.

3. The same chemical identity data are required as under 40 CFR §158.150-190, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

4. The 5/2/89 update of the index of uses for Pendimethalin was used to create this document.

TABLE A. (Continued).

5. No plant metabolism data have been submitted in response to the Guidance document. The following additional data are required: Data depicting the distribution and metabolism of [^{14}C]pendimethalin in or on mature plant parts from three dissimilar food crops (e.g., a root crop, oilseed crop, and a leafy vegetable). If metabolism is not similar in the three crops, additional studies using other crops may be required. A completely characterized test substance representative of technical pendimethalin (including impurities, if appropriate) used in commercial formulations must be applied at levels sufficiently high to permit characterization of ^{14}C-residues. The identities and quantities of extractable and nonextractable residues must be determined. Confirmation of the identities of residues using a suitable confirmatory method such as MS or HPLC is also required. In addition, representative samples from the tests must be analyzed using a currently accepted or proposed enforcement analytical method in order to ascertain that this method will determine all possible metabolites of concern.

6. No animal metabolism data have been submitted in response to the Guidance document. The following additional data are required: Metabolism studies utilizing ruminants. Animals must be dosed orally with ring-labeled [^{14}C]pendimethalin for a minimum of three days at a level sufficient to make residue identification and quantification possible. 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 milk, muscle, fat, kidney, and liver. 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 metabolism differs significantly from the rat data, then swine metabolism data will also be required.

7. No animal metabolism data have been submitted in response to the Guidance document, therefore, the following additional data are required: Metabolism studies utilizing poultry. Animals must be dosed orally with ring-labeled [^{14}C]pendimethalin for a minimum of three days at a level sufficient to make residue identification and quantification possible. Eggs 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, muscle, fat, 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 poultry metabolism differs significantly from the rat data, then swine metabolism data will also be required.

TABLE A. (Continued).

8. For all food uses, data current guidelines require data on whether the FDA multiresidue methodology would detect and identify a pesticide are required (40 CFR 158.240). The FDA Pestrack database (PAM Vol. I Appendix dated 10/25/89) contains data concerning the applicability of multiresidue methods to pendimethalin; specifically, Protocol D (nonfatty foods). The following additional data are required: Representative samples of plant and animal tissues containing residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite must be analyzed by multiresidue Protocols C and E from PAM Vol. I, Appendix II.

9. The qualitative nature of the residue in plants and animals has not been adequately described, therefore, the adequacy of the available methods cannot be ascertained. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting additional analytical methods will be required. If radiolabeled validation of existing analytical methodology for plants and animals (refer to "Qualitative Nature of the Residue in Plants" and "Qualitative Nature of the Residue in Animals" for additional details) indicates a major portion of the total radioactive residue is not recovered and identified by these methods, radiolabeled validation of new proposed analytical methodology will be required.

10. The storage stability data submitted in response to the Guidance document do not satisfy the requirements for this topic. The following additional data are required: 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.

11. The nature of the residue in plants and animals is not adequately understood. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting the stability of those residues during storage will be required.

12. The soybean forage data submitted in response to the Guidance Document do not fulfill the requirement for this topic. The following additional data are required: The registrant must provide a description of

TABLE A. (Continued).

the analytical method (M-1609) and provide recovery data to validate the submitted residue data on soybean foliage.

13. No data pertaining to processed products from oil seed crops have been submitted. The following additional data are required. A processing study depicting pendimethalin residues of concern in wet milled products (starch, crude oil, and refined oil) and in dry milled products (grits, meal, flour, and crude and refined oils) processed from field corn bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed. These data will fulfill the requirements for data depicting the concentration of residues in the oil of oil seeds (cottonseed, peanuts, soybeans, and sunflowers). The registrant should complete the required plant metabolism data before submitting data from a processing study.

14. No rice processing data were required in the Guidance Document. Current Agency Guidelines require data for this topic. The following additional data are required: A processing study depicting the potential for concentration of pendimethalin residues of concern in milled products (hulls, bran, and polished rice) from the processing of rice bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated at the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on rice grain.

15. No sorghum processing data were required in the Guidance Document. Current Agency Guidelines require data for this topic. The following additional data are required: A processing study depicting the potential for concentration of pendimethalin residues of concern in milled products (flour and starch) from the processing of sorghum bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated at the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on sorghum grain.

16. No tobacco data were submitted in response to the Guidance Document. The following additional data are required: Residue data involving the metabolism of pendimethalin in tobacco using radioisotope techniques; and residue data involving pyrolysis products derived from dicamba must be characterized and the level of residue in tobacco smoke must be quantified. Weathered residues of [^{14}C]pendimethalin must be used for identification of pyrolysis products.

TABLE A. (Continued).

17. Studies must be conducted using grapes and representative fruit and nut trees in which [^{14}C]pendimethalin is applied to the base of trees just prior to flowering at an exaggerated rate. If measurable ^{14}C-residues occur in mature fruit, the identities and quantities of all such residues must be determined.

18. The nature of the residue in animals is not understood. On receipt of the requested animal metabolism data, the need for and nature of tolerances for residues of pendimethalin in meat, milk, poultry, and eggs will be determined, and additional feeding trials may be required.

19. In lieu of submitting data pertaining to residues in fish tissue, the registrant has elected to impose a label restriction against use of pendimethalin on rice where commercial catfish or crayfish farming is practiced (EPA Reg. No. 241-243, dated 4/15/86).

DYNAMAC
CORPORATION

Final Report

PENDIMETHALIN
Task 4: Product Chemistry
Registration Standard Update

February 28, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

PENDIMETHALIN

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

Task - 4

INTRODUCTION

A Product Search Listing (PRD-2B4C) conducted 1/21/90 identifies three pendimethalin manufacturing-use products: the 90% technical (T; EPA Reg. No. 241-245), the 60% formulation intermediate (FI; EPA Reg. No. 241-281), and the 86.8% FI (EPA Reg. No. 241-291). All products are registered with American Cyanamid Company.

The Pendimethalin Guidance Document dated March, 1985 identifies outstanding data gaps for several product chemistry topics for the 90% T (EPA Reg. No. 241-245). In response to the Guidance Document, American Cyanamid Company submitted product chemistry data (1985; MRIDs 00153762 and 00152847) which were reviewed by the Agency. In response to Agency reviews, American Cyanamide submitted additional data (1986, MRIDs 00158623 and 00161758; and 1989, MRID 41111301). These data and our conclusions are presented below.

We note that no FIs were registered at the time the Guidance Document was issued. Since the issuance of the Guidance Document, American Cyanamide has submitted additional data pertaining to the registration of the 86.8% FI (EPA Reg. No. 241-291) and an unregistered 60% FI (1987; MRID 40392101 and undated MRID 00154789). Since these data were not submitted in response to the Guidance Document, they are not reviewed in this update.

Corresponding to each of the Topical Discussions listed below are the Guideline Reference Numbers from "Pesticide Assessment Guidelines - Subdivision D - Product Chemistry", referred to in Title 40 of the Code of Federal Regulations (40 CFR), Part 158, "Data Requirements for Registration", Subpart C, "Product Chemistry Data Requirements". These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of pendimethalin.

	Guidelines Reference No. from 40 CFR §158.155-190
Product Composition and Manufacture	61-(1-3)
Analysis and Certification of Product Ingredients .	62-(1-3)
Physical and Chemical Characteristics	63-(2-20)

Current Agency policy requires that recent product chemistry data be available for each pesticide. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be updated and resubmitted for each pesticide to satisfy current data requirements.

SUMMARY

The following Product Chemistry data must be submitted for the American Cyanamid Company 90% T (EPA Reg. No. 241-245):

- The nominal concentration must be submitted for each impurity and certified limits must be submitted on EPA form 8570-4 (Rev 2/85).

- Validation studies of method accuracy and precision are required for all methods used to determine impurities of toxicological significance to satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Composition

The Pendimethalin Guidance Document dated March, 1985 concludes that the available data regarding product identity and disclosure of ingredients satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) for the American Cyanamid 90% T (EPA Reg. No. 241-245). No additional data are required.

61-2. Description of Beginning Materials and Manufacturing Process

The Pendimethalin Guidance Document dated March, 1985 concludes that data submitted for the beginning materials and manufacturing process for the 90% T (EPA Reg. No. 241-245) are inadequate due to the absence of addresses for the manufacturers or producers of starting materials. American Cyanamid Company submitted additional data (1986; MRID 00153762) which was reviewed by G. Makhijani (DEB No. 789, dated 6/13/86) who concluded that the submission does not contain the required data. Another volume of data was submitted by American Cyanamid Company (1986; MRID 00158623) which contains addresses for all manufacturers and/or producers of beginning materials as well as complete technical documentation for the starting materials. This information satisfies the outstanding requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding beginning materials and the manufacturing process for the American Cyanamid

90% T (EPA Reg. No. 241-245). No additional information is required.

61-3. Discussion of Formation of Impurities

The Guidance Document, dated March 1985 requires all generic and product specific requirements pertaining to the discussion of the formation of impurities in the 90% T (EPA Reg. No. 241-245). In response to the Guidance Document, American Cyanamid Company (1986; MRID 00153762) submitted a discussion of the formation of impurities, including the potential for N-nitrosamine formation in the 90%T (EPA Reg. No. 241-245). This information was reviewed by G. Makhijani (DEB No. 789, dated 6/13/86) who concluded that the discussion fulfilled requirements. A second submission by American Cyanamid Company (1986; MRID 00152847), dealt exclusively with N-nitrosamine formation and included analysis of the 90% T for the presence of N-nitrosamines formed during manufacture and storage of the product. This information was also reviewed by G. Makhijani (DEB No. 790, dated 6/25/86) who reiterated that no additional data was required for this topic. No further discussion is required.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Guidance Document, dated March 1985 requires all generic and product specific requirements pertaining to the preliminary analysis of the 90% T (EPA Reg. No. 241-245). In response to the Guidance Document, American Cyanamid Company (1985; MRID 00153762) submitted preliminary analysis data for the 90% T (EPA Reg. No. 241-245). These data were reviewed by G. Makhijani (DEB No. 789, dated 6/13/86) who determined that data requirements were not satisfied because several impurities remained unidentified (listed as Compound A, Compound B, and organic residue). In response to this review, American Cyanamid (1989; MRID 41111301) submitted data pertaining to the unidentified compounds (see Confidential Appendix B). These data satisfy the requirements of 40 CFR §158.70 (Guideline Reference No. 62-1) regarding preliminary analysis for the American Cyanamid 90% T (EPA Reg. No. 241-245). No additional data are required.

62-2. Certification of Limits

The Guidance Document, dated March 1985 requires that a current Confidential Statement of Formula be submitted for the 90% T (EPA Reg. No. 241-245). In response to the Guidance Document, American Cyanamid Company (1985; MRID 00153762 and 1987; MRID 40392101) submitted a Certified Statement of Formula for the 90%

T (EPA Reg. No. 241-245) along with a brief explanation of how limits were determined. The statement of formula was reviewed by G. Makhijani (DEB No. 789, 6/13/86) who concluded that the data are inadequate due to the presence of several unidentified impurities (listed as Compound A, Compound B, and organic residue) on the CSF. In response, American Cyanamid Company (1989; MRID 41111301) submitted an updated list of certified limits (see Confidential Appendix A). The submitted data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the American Cyanamid 90% T (EPA Reg. No. 241-245) because nominal concentrations were not reported for impurities; futhermore, data were not submitted on EPA form 8570-4 (Rev 2/85). Additional data are required.

62-3. Enforcement Analytical Methods

The Guidance Document, dated March 1985 requires enforcement analytical methods for the determination of impurities of pendimethalin. In response to the Guidance Document, American Cyanamid Company (1986; MRID 00153762) submitted a high resolution gas chromatography method (Method M-1551) for determination of pendimethalin and several of its impurities in the 90% T (EPA Reg. No. 241-245). These methods were reviewed and accepted by G. Makhijani (DEB No. 789, dated 6/13/86); however, additional methods were required for analysis of several unidentified impurities. American Cyanamid Company (1989; MRID 41111301) submitted new methods for determinations of these impurities (see Confidential Appendix C). The data do not satisfy requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods because validation studies of method accuracy and precision were not included.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Guidance Document identifies outstanding generic and product specific data requirements pertaining to physical and chemical properties of the American Cyanamid 90% T (EPA Reg. No. 241-245). In response, American Cyanamid submitted data (1986; MRID 00153762) which were reviewed by G. Makhijani (DEB No. 789, dated 6/13/86) and found to satisfy the requirements for Guidelines Reference Nos. 63-2 through 63-16 and 63-20; data on storage stability were still outstanding. Storage stability data (Guideline Reference No. 63-17) were later submitted (1986; MRID 00161758). No significant change was observed in samples from three lots of the 90% T stored in steel drums under warehouse conditions for one year. The analytical method used was M-1551. These data satisfy the requirements of the 40 CFR §158.190 (Guideline Reference No. 63-17). No further information is required.

Product Chemistry Citations (used):

00152847 Cortes, D. (1985) Part II: Section 61-3, Discussion of the Formation of Impurities for the Manufacturing-use Product or Technical in Prowl Herbicide--Potential N-Nitrosamines in Pendimethalin: Project No. 0166: Report No. 4. Unpublished study prepared by American Cyanamid Co. 89 p.

00153762 American Cyanamid Co. (1985) Pendimethalin Registration Standard: Volume I: Product Chemistry Data. Unpublished compilation. 377 p.

00158623 American Cyanamid Co. (1986) [Product Chemistry Data Requirements for the Manufacturing-use Product or Technical in Prowl Herbicide] Description of the Beginning Materials and the Manufacturing Process: Unpublished compilation. 95 p.

00161758 Cortes, D. (1986) Product Chemistry Data Requirements for the Manufacturing Use Product or Technical in Prowl Herbicide: ..... Physical and Chemical Characteristics. Unpublished study prepared by American Cyanamid Co. 34 p.

41111301 Wayne, R. (1989) Additional Data for the 62-Series Requirements. Unpublished study prepared by American Cyanamid Co. 49 p.

References (not used):

[The following references pertain to manufacturing-use products registered subsequent to the issuance of (Pesticide) Guidance Document dated (when). Since these data were not submitted in response to the Guidance Document, they were not reviewed and evaluated in this report.]

00154789 American Cyanamid Co. (1982) Name, Chemical Identity and Composition of Prowl Herbicide. Unpublished compilation. 19 p.

40392101 Garber, M. (1987) Prowl Herbicide:... Amendment of Certified Limit from One of the Inerts and Corresponding Amendment of the Manufacturing Process: Description Necessitated by the Certified Limit Change. Unpublished compilation prepared by American Cyanamid Co. 10 p.

[The following references were not reviewed because the Agency has determined that data requirements pertaining to the topics discussed within these documents have already been satisfied.]

40016001 Cortes, D. (1986) Part II: Supplement A: Section 61-3, Discussion of the Formation of Impurities for the Manufacturing-use Product or Technical in Prowl Herbicide - Potential N-Nitrosamines in Pendimethalin: Laboratory Report No. CHDV 26:19. Unpublished study prepared by American Cyanamid Co. 75 p.

40194401 Cortes, D. (1987) Part II: Supplement B: Section 61-3, Discussion of the Formation of Impurities for the Manufacturing-use Product or Technical in Prowl Herbicide-- Potential N-Nitrosamines in Pendimethalin: Project No.: 0166. Unpublished compilation prepared by American Cyanamid Co. 21 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE PENDIMETHALIN TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Yes	00153762 00158623	No
61-3. Formation of Impurities	TGAI	Yes	00152847 00153762	No
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	TGAI	Yes	00153762 41111301	No
Physical and Chemical Characteristics[3]				
63-2. Color	TGAI	Yes	N/A	No
63-3. Physical State	TGAI	Yes	N/A	No
63-4. Odor	TGAI	Yes	N/A	No
63-5. Melting Point	TGAI	Yes	N/A	No
63-6. Boiling Point	TGAI	Yes	N/A	No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	N/A	No
63-8. Solubility	TGAI or PAI	Yes	00153762	No
63-9. Vapor Pressure	TGAI or PAI	Yes	N/A	No
63-10. Dissociation Constant	TGAI or PAI	Yes	00153762	No
63-11. Octanol/Water Partitioning Coefficient	PAI	Yes	00153762	No
63-12. pH	TGAI	Yes	00153762	No
63-13. Stability	TGAI	Yes	00153762	No
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

1. Additional data requirements are listed in the following Table B, "Generic Data Requirements for Pendimethalin Manufacturing-Use Products".

TABLE A. (Continued).

2. Test substance: PAI = purified active ingredient; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

3. As required by 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, and stability). There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing use products.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR PENDIMETHALIN MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Composition	MP	Yes	N/A	No
61-2. Beginning Materials & Production/Formulation Process	MP	Yes	00153762 00158623	No
61-3. Formation of Impurities	MP	Yes	00152847 00153762	No
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	MP	Yes	00153762 41111301	No
62-2. Certified Limits	MP	Partially	00153762 40392101 41111301	Yes[3]
62-3. Enforcement Analytical Methods	MP	Partially	00153762 41111301	Yes[4]
Physical and Chemical Characteristics[5]				
63-2. Color	MP	Yes	N/A	No
63-3. Physical State	MP	Yes	N/A	No
63-4. Odor	MP	Yes	N/A	No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	N/A	No
63-12. pH	MP	Yes	00153762	No
62-14. Oxidizing or Reducing Action	MP	Yes	00153762	No
62-15. Flammability	MP	No	N/A	No[6]
63-16. Explodability	MP	Yes	00153762	No
63-17. Storage Stability	MP	Yes	00161758	No
63-18. Viscosity	MP	No	N/A	No[7]
63-19. Miscibility	MP	No	N/A	No[8]
63-20. Corrosion Characteristics	MP	Yes	00153762	No
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

TABLE B. (Continued).

1. Data requirements pertain to the American Cyanamid 90% T (EPA Reg. No. 241-245). Data requirements pertaining to the 60% and 86.8% FIs (EPA Reg. Nos. 241-281 and 241-291) are not included in this update since these products were not registered at the time the Guidance Document was issued (March, 1985). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Pendimethalin Technical Grade of the Active Ingredient".

2. Test substance: PAI = purified active ingredient; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

3. Nominal concentrations must be reported for all impurities listed on the Confidential Statement of Formula. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85).

4. Validation studies of method accuracy and precision are required for all methods used to determine impurities of toxicological significance to satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods.

5. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use products which contain only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the Pendimethalin Technical Grade of the Active Ingredient."

6. Data are not required on flammability since the product does not contains combustible liquids.

7. Data on viscosity are not required since the product is a solid.

8. Data on miscibility are not required since the product is not an emulsifiable liquid that is to be diluted with petroleum solvents.

PENDIMETHALIN

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK-4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 3 Pages
Appendix B: 1 Page
Appendix C: 1 Page

Confidential Appendices to the Scientific Review of the Registration Standard Update for the pesticide pendimethalin by the Dietary Exposure Branch [Confidential FIFRA Trade Secret/CBI].

Pendimethalin Product Chemistry and Residue Chemistry Update

Page _____ is not included in this copy.

Pages 42 through 46 are not included in this copy.

The material not included contains the following type of information:

__X__ Identity of product inert ingredients.

_____ Identity of product inert impurities.

__X__ Description of the product manufacturing process.

_____ Description of product 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.