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

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

JUN 13 1986

MEMORANDUM

SUBJECT: American Cyanamid Company - Response to the Product Chemistry Chapter of the Pendimethalin Registration Standard (EPA Accession No. 260401) RCB No. 789

FROM: Gobind P. Makhijani *Gobind Makhijani*  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769C)

TO: Robert S. Taylor/V.K. Walters, PM Team 25  
Fungicide-Herbicide Branch  
Registration Division (TS-767C)

and

Amy Rispin  
Science Integration Staff  
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769C)

In response to the Pendimethalin Registration Guidance Document dated March 29, 1985, American Cyanamid, Agricultural Research Division has now submitted additional product chemistry data dated October 30, 1985 (EPA Accession No. 260401). These data and our conclusions are discussed below. Also, revised tables A and B are provided at the end of this report.

61-2 Description of Beginning Materials and Manufacturing Process:

Certain of the information required under this topic has been submitted by the registrant under Exhibit 4 (EPA Accession No. 260401) entitled "Discussion of Formation

of Impurities for the Manufacturing-Use Product - Prowl Technical. Further details are required for all of the beginning materials (names and addresses of the suppliers) used for the manufacture of pendimethalin.

A data gap still exists here.

61-3 Discussion of the Formation of Impurities

The registrant has submitted a comprehensive discussion of the possible formation of impurities during the manufacture of pendimethalin along with the equations for the possible reactions (EPA Accession No. 260401 - Exhibit 4 Part I - 57 pages). The registrant has also submitted information entitled "Discussion of Formation of Impurities - Volume I, Exhibit 4, Part II - Potential N-Nitrosamines in Pendimethalin" - EPA Accession No. 260473 dated November 19, 1985 (RCB No. 790). This report is being discussed separately.

We defer to the Toxicology Branch regarding the toxicological significance of the possible impurities formed during the manufacture of pendimethalin. The original copy of the report is available with Residue Chemistry Branch (RCB).

This fulfills the requirements of this topic and no other additional information is required.

62-1 Preliminary Analysis

The registrant has submitted preliminary analysis of five batches of pendimethalin technical produced at Hannibal, MO during May and July 1985. A discussion of the analytical data is attached in Confidential Appendix A.

Since there are unidentified impurities, [REDACTED]

[REDACTED] in the technical product, the requirements for this topic remain outstanding, until these impurities are identified.

62-2 Certification of Limits

The registrant has submitted the required information giving the upper and lower limits for the active ingredient and the upper limits for the impurities on the EPA Form

8570-4 (Rev. 2-85). The impurities [REDACTED] be identified.

A data gap still exists here.

62-3 Analytical Methods to Verify Certified Limits

The registrant has submitted methods for the determination of pendimethalin as well as other components in the technical product. These procedures are discussed in Confidential Appendix B.

The methods submitted to date are acceptable; however, additional procedures for quantitation of the unknown materials discussed above are also required. A data gap still exists here.

63-8 Physical and Chemical Characteristics

to

63-20 Physical and Chemical properties not reported previously are as follows:

<u>Section</u>	<u>Title</u>	<u>Test Substance</u>	<u>Result</u>
63.8	Solubility	PAI	Water 0.275 ppm at 25 °C
		TGAI	n-Heptane 11.2 g per 100 mL at 25 °C
			2-Propanol 6.1 g per 100 mL at 25 °C
			Acetone 161.0 g per 100 mL at 25 °C
			Toluene 128.4 g per 100 mL at 25 °C
			Methyl alcohol 5.5 g per 100 mL at 25 °C
			Dimethyl sulfoxide 21.4 g per 100 mL at 25 °C
			Methylene chloride 232.0 g per 100 mL at 25 °C
63-10	<u>Dissociation Constant</u>	TGAI	- Too small to measure.
63-11	<u>Octanol/Water Partition</u>	PAI	<u>Coefficient</u> - 152,000 at nominal concentrations of 465 and 47 ppm in the octanol phase
63-12	<u>pH</u>	TGAI	4.7
63-13	<u>Stability</u>	TGAI	In closed glass bottles stored at 25 °C - Very slight loss after 1 and 2 years Stored at 37 °C - No effect after 1-year storage Stored at 45 °C - Very slight loss after 3-months storage.

- 63-14 Oxidizing or Reducing Action TGAI Reducing Action - None with dilute potassium permanganate solution.
- TGAI Oxidizing Action - The nitro group undergoes reduction to corresponding amine with sodium sulfide in ethanol, stannous chloride in ethanolic HCl and with hydrogen in presence of palladium on carbon.
- Aromatic nitro group - react in a neutral medium with zinc dust in the presence of aqueous ammonium chloride.
- 63-15 Flammability TGAI - No flash at 230 °F in a setaflash closed cup tester. No flash at 207 °F in Tag closed up test.  
No autoignition to 392 °F.  
Decomposition occurs over 392 °F.
- 63-16 Explosibility TGAI - Impact sensitivity - Insensitive at 25 °C at 2 kg/100 cm and 4 kg/80 cm.
- 63-17 Storage Stability TGAI - Test in progress.
- 63-20 Corrosion Characteristics - TGAI - Noncorrosive to metals.

Attachment I: Tables A and B (4 pages)

cc: Pendimethalin Registration Standard, S.F., Reviewer,  
RBP, PMSD/ISB, Taylor (PM 25), R.F. Circu, TOX (Coberly)

Attachment II: Confidential Appendix A and B (7 pages)

cc: Pendimethalin Registration Standard, S.F., Reviewer,  
RBP, PMSD/ISB (E. Eldridge), Taylor (PM 25)  
TOX (Coberly).

cc: Pendimethalin Registration Standard, R.F., Reviewer,  
PMSD/ISB (E. Eldrige), S.F., Taylor (PM 25)  
Circu., RBP, TOX (Coberly)

TABLE A  
GENERIC DATA REQUIREMENTS FOR PENDIMETHALIN (EPA REGISTRATION NO. 241-245)

§158.120 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required		Reference
			Yes	No	

Product Identity:

61-2 - Description of Beginning Materials and Manufacturing Procedure	TGAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401
	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401 and 260473

Analysis and Certification of Product Ingredients

62-1 - Preliminary Analysis	TGAI	CR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401
62-2 - Certification of Limits	TGAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401
62-3 - Analytical Methods for Enforcement of Limits	TGAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401

Physical and Chemical Characteristics

63-2 - Color	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-3 - Physical State	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-4 - Odor	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-5 - Melting Point	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-6 - Boiling Point	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401

R = Required; CR = Conditionally Required; TGAI = Technical Grade of the Active Ingredient

TABLE A  
GENERIC DATA REQUIREMENTS FOR PENDIMETHALIN (EPA REGISTRATION NO. 241-245)

§158.120 - PRODUCT CHEMISTRY (Cont'd)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required		Reference
			Yes	No	

Physical and Chemical Characteristics  
(Continued)

63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-8 - Solubility	TGAI or PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-9 - Vapor Pressure	PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-10 - Dissociation constant	PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-11 - Octanol/water partition coefficient	PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-12 - pH	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-13 - Stability	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401

Other Requirements:

64-1 - Submittal of samples TGAI, PAI CR   1/

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 R = Required; CR = Conditionally Required; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient

DATA REQUIREMENT FOOTNOTES:

1/ If samples are needed the Agency will request them.

TABLE B  
 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS  
 CONTAINING PENDIMETHALIN (EPA REGISTRATION NO. 241-245)

\$158.120 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required		Reference
			Yes	No	
<u>Product Identity:</u>					
61-1 - Product Identity and Disclosure of Ingredients	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401
61-3 - Discussion of Formation of Impurities	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	MP	CR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401
62-2 - Certification of Limits	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401
62-3 - Analytical Methods to Verify Certified Limit	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Acc. No. 260401
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-3 - Physical State	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-4 - Odor	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401

R = Required; CR = Conditionally Required; MP = Manufacturing-use Product



TABLE B  
 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS  
 CONTAINING PENDIMETHALIN (EPA REGISTRATION NO. 241-245)

§158.120 - PRODUCT CHEMISTRY (Cont'd)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required		Reference
			Yes	No	

Physical and Chemical Characteristics  
 (Continued)

63-7 - Density, Bulk Density, or Specific Gravity	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-12 - pH	MP	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-14 - Oxidizing or Reducing Action	MP	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-15 - Flammability	MP	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-16 - Explodability	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
63-17 - Storage Stability	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	---
63-18 - Viscosity	MP	N/A	<input type="checkbox"/>	<input type="checkbox"/>	---
63-19 - Miscibility	MP	N/A	<input type="checkbox"/>	<input type="checkbox"/>	---
63-20 - Corrosion Characteristics	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Acc. No. 260401
<u>Other Requirements</u>					
64-1 - Submittal of samples	MP	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	1/

.....  
 R = Required; CR = Conditionally Required; MP = Manufacturing-use Product

DATA REQUIREMENT FOOTNOTES:

1/ If samples are needed the Agency will request them.

Pendimethalin dietary exposure review

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Pages 9 through 15 are not included in this copy.

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The material not included contains the following type of information:

- Identity of product inert ingredients
  - Identity of product impurities
  - 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
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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