

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

DATE OUT: 10/NOV/1998

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
BARCODE No.: 249727 EPA RECEIVED DATE: 29/MAY/1998 REG./File Symbol No.: 33660-GO
PRODUCT NAME: pendimethalin-L, 37.4% N-(1-ethylpropyl)-3,4-dimethyl-2,6-
dinitrobenzenamine MRIDs: 445422-01 to -10 & -01C, -02C; 445571-01 & -02; 445573-01
& -01C COMPANY NAME: Industria Prodotti Chimici S. P. A.
Action Code: 160**

FROM: Sami Malak, Chemist/S/ *Sami Malak*
Technical Review Branch/RD (7505C)

TO: 25 Jim Tompkins/Lisa Jones
Herbicide Branch/RD (7505C)

INTRODUCTION:

On behalf of Industria Prodotti Chimici S. P. A., Lewis & Harrison requests a "Me-Too" registration of this end-use product claiming its similarity to American Cyanamid Prowl 3.3EC, Reg. No. 241-337. In support of this request, the applicant included product chemistry data, product's CSF a basic formulation dated 15/MAR/1998, and label EPA received 29/MAY/1998.

FINDINGS:

1. This end-use product does not qualify for a "Formulator's Exemption" since it was produced by an integrated formulation system meaning the technical source, pendimethalin: N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, is not registered, Reg. No. 33660-UN, CAS #40487-42-1 (92.6% pure), The full generic and product specific data requirements for the technical source and this product, respectively, were concurrently reviewed by this reviewer. This product contains 37.4% PAI pendimethalin.
2. In a separate memo, it was concluded that pendimethalin technical supplied by Industria Prodotti Chimici S.p.A. of Novate Milanese, Italy, Reg. No. 33660-UN, 92.6% pure, is similar to [REDACTED] manufactured by [REDACTED] pure, meaning both technicals are of similar composition (S. Malak, D249731, 10/NOV/1998).
- 3a. The nominal concentration of this product is 37.4% as opposed to 38.5% of the registered product claimed to be similar to it, American Cyanamid Prowl 3.3EC, Reg. No. 241-337, a drop of 3%, however, still within the

upper & lower limits of the registered product, 38.6 & 36.3%, respectively. As per the regulations of 40CFR§158.175(b)(2), this product is similar to American Cyanamid Prowl 3.3EC, Reg. No. 241-337.

- 3b. Using the proposed enforcement analytical method, the results of seven batch analysis were reported in MRID #445570-02, page 20 of 104, at 34.56%. This value contradicts the claimed nominal concentration of 37.4% and would reverse the conclusion in 3a from similarity of this product to American Cyanamid Prowl 3.3EC, Reg. No. 241-337 to NON similarity. The applicant should be advised to provide adequate explanations of this discrepancy.
- 4a. The applicant should be advised to submit or reference product chemistry data requirement of GRN 830-7100 identified as data gap, pertaining to viscosity of this end-use product.
- 4b. With the exception of the data gaps cited in Finding 4a above, the remaining product chemistry data is adequate and satisfy the requirements for a "Me-Too" registration of this product.
5. An adequate GC analytical method is available for enforcement. The method entitled: "Pendimethalin Technical And Formulated Products, GLC Determination of Pendimethalin In Technical And Its Formulations, Validation of The Analytical Method." The method, included in MRID #445570-01C & 445570-02, was authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 12/SEP/1995, 107 pages, Prepared and Validated by ChemService (Study CH-38/95)." The method utilizes diisopropyl phthalate as an internal standard & is applicable to the determination of pendimethalin per se in pendimethalin technical grade of active ingredient and formulated products. Detailed considerations of the method is to be found in connection with pendimethalin technical manufactured by Industria Prodotti Chimici S.p.A. of Novate Milanese, Italy, Reg. No. 33660-UN (S. Malak, D249731, 10/NOV/1998).
- 6a. The ingredient statement, the physical/chemical hazard statement, and the storage and disposal statement cited on product's label, EPA received 29/MAY/1998, satisfy the requirements of 40CFR§156.10 & the nominal concentration as per the regulations of PR Notice 91-2.
- 6b. The CRM will need to review label uses noting that because of Finding 3 above, recommended uses for this product must be identical or substantially similar to those in the registered product, American

Cyanamid Prowl 3.3EC, Reg. No. 241-337.

- 7a. The submitted product's CSF a basic formulations dated 15/MAR/1998 was filled out correctly and completely in compliance with the regulations of 40CFR§152.43. The nominal concentration of the active ingredient agrees with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2).
- 7b. All ingredients claimed on the CSF are cleared for use in pesticide formulations.
- 7c. Box 10 of the CSF should be corrected to read 1.0726 g/ml; and box 9 should be revised to read 84°C (183.2 °F).
- 7d. The applicant should be advised to indicate on product's CSF the presence of [REDACTED]

CONCLUSIONS:

Pending registration of the technical source and resolution of Findings 3(b), 4(a), 7(c) & 7(d) above, we will have no objections for a "Me-Too" registration of this product.

Notes to CRM: Please note Finding 6(b) above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 09/MAR/1998 was included with this submission claiming confidentiality of some of the data requirements on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI information is to be found in Confidential Appendix A.
2. A GLP statement dated 09/MAR/1998 was included with this submission to the effect that some of the submitted studies were conducted in full compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #445442-01 The submitted study entitled "Guideline Series 61: Product Identity and Composition, Ipimethalin-L", was authored by Isa Bonora,

Completed 11/JUL/1996 9 + 39 pages.

MRID #445442-02C The submitted study entitled "Guideline Series 62: Analysis and Certification of Product Ingredients, Ipimethalin-L", was authored by Isa Bonora, Completed 11/JUL/1996 7 pages.

MRID #445442-03 The submitted study entitled "Pendimethalin Technical And Formulated Products, GLC Determination of Pendimethalin In Technical And Its Formulations, Validation of The Analytical Method", authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 12/JUL/1996 100 pages.

MRID #445442-04 The submitted study entitled "Ipimethalin-L, Determination of The Appearance Colour And Odour, Data Requirement, Guidelines 63-2, 63-3, 63-4", authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 18/NOV/1996 16 pages.

MRID #445442-05 The submitted study entitled "Ipimethalin-L, Determination of The Density, Data Requirement, Guideline 830-7300, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 30/SEP/1996 12 pages.

MRID #445442-06 The submitted study entitled "Ipimethalin-L, Determination of The pH Value and The Acidity/Alkalinity, Data Requirement, Guideline 63-12, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 30/SEP/1996 12 pages.

MRID #445571-01 The submitted study entitled "Ipimethalin-L, Accelerated Storage Stability, Data Requirement, Guideline 63-13, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 18/JUN/1997 51 pages.

MRID #445442-07 The submitted study entitled "Ipimethalin-L, Determination of The Flash Point, Data Requirement, Data Requirement, Guideline 63-15, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 30/SEP/1996 12 pages.

MRID #445442-08 The submitted study entitled "Ipimethalin-L, Determination of The Explosive Properties, Data Requirement, Guideline 63-16, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 04/DEC/1996 14 pages.

MRID #445442-09 The submitted study entitled "Ipimethalin-L, Determination of The Viscosity, Data Requirement, Guideline 830-7100, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 30/SEP/1996 14 pages.

MRID #445442-10 The submitted study entitled "Ipimethalin-L, Determination of The Emulsifiability, Re-Emulsifiability, Emulsion Stability, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 30/SEP/1996 12 pages.

MRID #445442-10 The submitted study entitled "Ipimethalin-L, Determination of The One Year Storage Stability And Corrosion Characteristics, Data Requirement, Guideline 63-17, 63-20, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 18/JUN/1997, 143 pages.

MRID #445573-01C The submitted study entitled "Analysis To Demonstrate The Similarity Between Pendimethalin Manufactured By I.Pi.Ci. And Pendimethalin Manufactured by American Cyanamid, authored by Dr. S. Garofani, Performed by Chemservice S.P.A. of Novate Milanese, Italy, Completed 04/DEB/1998, 9 + 173 pages.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The identity of all ingredients in this product are listed on product's CSF, a basic formulation dated 15/MAR/1998.

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

830-1650 Description of Formulation Process: Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities: Refer to Confidential appendix A.

830-1700 Preliminary Analysis: Refer to Confidential appendix A.

830-1750 Certified Limits: Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

An adequate analytical method is available for enforcement. The method entitle: "Pendimethalin Technical and Formulated Products - GLC Determination of Pendimethalin in Technical and Its Formulations, Prepared and Validated by ChemService (Study CH-19/95A)."

The method is applicable to determination of pendimethalin per se in pendimethalin formulated products. Detailed considerations of the method is to be found in connection with pendimethalin technical manufactured by Industria Prodotti Chimici S.p.A. of Novate Milanese, Italy, Reg. No. 33660-UN (S. Malak, D249731, 10/NOV/1998).

Using the proposed enforcement analytical method, the results of seven batch analysis were reported in MRID #445570-02, page 20 of 104, at 34.56%. This value contradicts the claimed nominal concentration of 37.4% and would reverse the conclusion in 3a from similarity of this product to American Cyanamid Prowl 3.3EC, Reg. No. 241-337 to NON similarity. The applicant will be asked to provide adequate explanations of this discrepancy.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190):

GUIDELINE REFERENCE NO.(GRN)/TITLE	VALUE OR QUALITATIVE DESCRIPTION/METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Yellow brown.
-6303 Physical State	Liquid.
-6304 Odor	Slightly aromatic.
-6314 Oxidation/Reduction:	The product does not contain oxidizing or reducing agents.

6

Incompatibility	
-6315 Flammability/Flame Extension	84°C (183.2 °F)
-6316 Explodability	The product does not Contain explosive materials.
-6317 Storage Stability	Stable for a period of one year, the period of testing.
-6319 Miscibility	Data Gap.
-6320 Corrosion Characteristics	Non corrosive to the packaging container.
-6321 Dielectric Breakdown Voltage	NA. Formulation is not recommended for use around electrical equipment.
-7000 pH	7.26
-7100 Viscosity	10.81 cP
-7300 Density/Relative Density Bulk Density	1.0726 g/ml

Confidential Appendix A

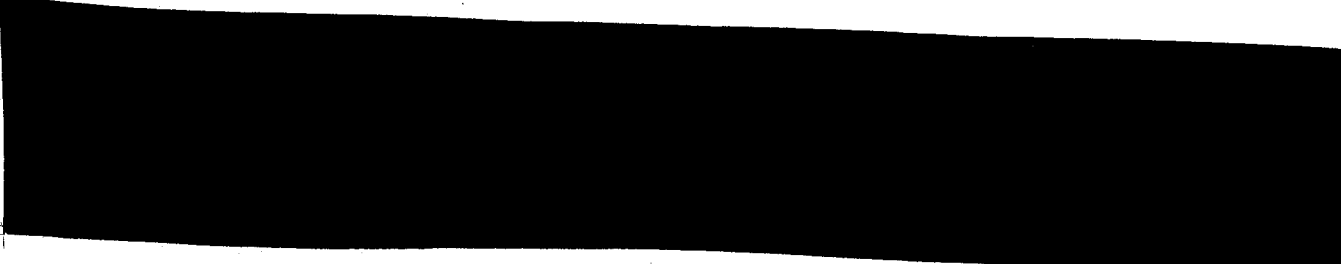
830-1600 Description of Materials Used to Produce the Product:

Materials used to formulate this product are listed on product's CSF, a basic formulation dated 15/MAR/1998.

830-1650 Description of Formulation Process:



830-1670 Discussion of Formation of Impurities: MRID #445571-02



With the exception of the carry over impurities from the technical source, the applicant reported no impurities or other ingredients $\geq 0.1\%$.

830-1700 Preliminary Analysis:

Not required for this formulation.

830-1750 Certified Limits:

The applicant reported the same ingredients at percentages and low/upper limits as those reported on product's CSF.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

8