



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

SEP 11 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 464-558. Chlorpyrifos
(Dursban R Insecticidal Chemical®)
Product Chemistry Data Gaps in Response to the
Chlorpyrifos Registration Standard Data Gaps.
Accession No. 257591. RCB No. 947

FROM: Sami Malak, Ph.D., Chemist *Sami Malak*
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TO: Amy S. Rispin, Chief
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and

Jay S. Ellenberger, (PM-12)
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Registration Division (TS-767)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769) *A.P. Schmitt for*

In response to the chlorpyrifos Registration Standard of February 29, 1984, Dow Chemical Company responded on April 8, 1985, by submitting product chemistry data cited in the Standard as data gaps for their Manufacturing-use Product (MUP), Dursban R Insecticidal Chemical®, Registration No. 464-558.

Chlorpyrifos is the common name for the insecticide 0,0-diethyl 0-(3,5,6-trichloro-2-pyridyl)phosphorothioate. Technical chlorpyrifos is manufactured by Dow Chemical Company. Dow apparently formulates several intermediate products known as Manufacturing-Use Products (MUP). Dow also sells technical chlorpyrifos to several other companies for formulating intermediate products (MUP's), or end-use products, several of which are registered with the EPA.

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Detailed data gaps cited in Table B of the Standard, for MUP comprise all data requirements under Series 61 and 62 of the Product Chemistry Guidelines, Subdivision D. The Table did not list data requirements under Series 63, because at that time (February 29, 1984), Residue Chemistry Branch did not address the physical and chemical characteristics of the MUP's. Data under Series 63 are now being processed by the Residue Chemistry Branch.

In our discussion below, we will list the data gap required under the corresponding Section in the product chemistry requirements of Part III, Data Requirements for Pesticide Registration Final Rule (40 CFR Part 158, 49 FR 42856, October 24, 1984) followed by Dow's response and our comments.

Series 61: Product Identity and Composition

\$61-1 Product Identity and Disclosure of Ingredients

Dow's Response:

Dursban R Insecticidal Chemical®, EPA Registration No. 464-558, is a [REDACTED] with a minimum assay of 99 percent chlorpyrifos 0,0-diethyl[0-(3,5,6-trichloro-2-pyridyl)phosphorothioate]. Dursban R is a manufacturing-use product, produced by Dow Chemical Company that may be used only for formulation of other manufacturing-use products or end-use products. A copy of the one-page Confidential Statement of Formula is included on page 1 of the Confidential Appendix, Attachment 2 of this review.

RCB Comments:

No additional information is required under \$61-1.

\$61-2 Description of Beginning Materials and Manufacturing Process

Dow's Response:

- A. Beginning materials are reported by Dow in one page, a copy of which is included on page 2 of the Confidential Appendix, Attachment 2 of this review.
- B. Manufacturing process is reported by Dow in pages 3, 4, and 5 of the Confidential Appendix, Attachment 2 of this review. The manufacturing process consists of [REDACTED]. The manufacturing process of Dursban R has previously been reviewed by G.P. Makhijani (Chlorpyrifos. Response to Data Gaps in Product Chemistry, July 30, 1985).
- C. Changes in beginning materials or manufacturing process: No changes in the beginning materials or manufacturing process were reported.

RCB Comments:

Dow Chemical Company complied with data requirements under §61-2 of the Product Chemistry Guidelines, Subdivision D.

§61-3 Discussion of Formation of ImpuritiesDow's Response:

Dursban R is a manufacturing-use product containing 99 percent chlorpyrifos, Registration No. 464-558. It is formulated by Dow Company by [REDACTED]

[REDACTED] These impurities were reported by Dow under Accession No. 257588 for [REDACTED] and reviewed in connection with [REDACTED] for chlorpyrifos [REDACTED] product chemistry data gaps (memorandum of G.P. Makhijani, July 30, 1985). Dow Company reported that since Dursban R manufacture is a [REDACTED]

[REDACTED] Nevertheless, the Dow Chemical Company included a list of impurities occurring in Dursban R as found in the analyses of 5 batch samples (see discussion under § 62-1). We note that Dursban R contains [REDACTED]

[REDACTED] Since the impurities in [REDACTED] have been previously discussed we see no reason for referring the list of impurities in Dursban R to TOX.

RCB Comments:

Dow Chemical Company complied with data requirements under §61-3.

Series 62: Analysis of Certification of Product Ingredients§62-1 Preliminary AnalysisDow's Response:

The analysis included in this submission is for 5 randomly selected production batches of the manufacturing-use product, Dursban R, sampled during 1981. Samples were analyzed for chlorpyrifos per se using Dow's Method No. ML-AM-80-30C (QA No. 2351). A range of 99.6 to 100 percent chlorpyrifos was reported for the product samples. Due to the high degree of purity, the amount of chlorpyrifos per se, was determined by an indirect assay method, i.e., by subtracting total impurities from 100. In the analyses, Dow identified [REDACTED] impurities, the levels of

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PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

[redacted] of which were determined by gas chromatography, whereas, impurities were determined by liquid chromatography. The method which describes both GC and LC procedures is known as ML-AM-80-30C (see discussion under §62-3). Total impurities in Dursban R in the 5 batch samples were determined at [redacted] percent.

RCB Comments:

No additional information is required under §62-1.

§62-2 Certification of Limits

Dow's Response:

Dow Chemical Company has given the upper and lower certification of limits for chlorpyrifos per se at [redacted] respectively. The upper certified limits for 4 major impurities occurring at > 0.1 percent were also given. A copy of the one-page certification of ingredient limits for Dursban R is included on page 6 of the Confidential Appendix of this review.

RCB Comments:

No additional information is required under §62-2.

§62-3 Analytical Methods for Enforcement of Limits

Dow's Response:

The analytical method employed for the determination of the impurities in Dursban R is Dow's Method No. ML-AM-80-30C (QA No. 2351), entitled "Indirect Assay of Dursban R Insecticidal Chemical by Gas and Liquid Chromatography." The method is validated for the determination of 7 impurities by gas chromatography and 5 impurities by liquid chromatography. Due to the relatively high purity of Dursban R, the percentage of chlorpyrifos per se is calculated by difference from 100 rather than being determined directly.

RCB Comments:

No additional information is needed under §62-3.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

Impurity

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Series 63: Physical and Chemical CharacteristicsDow's Response:

The physical and chemical characteristics for the manufacturing-use product, Dursban R, required under this series, were reported as follows:

63-2	Color	White
63-3	Physical State	Crystalline Solid
63-4	Odor	Very mild chemical
63-5	Melting Point	42-43.5 °C
63-7	Specific Gravity	1.398 (45 °C)
63-8	Solubility	g/100 g 25 °C
	Acetone	650
	Benzene	790
	Carbon Disulfide	590
	Carbon Tetrachloride	310
	Chloroform	630
	Diethyl Ether	510
	Ethanol, absolute	63
	Methanol	45
	Hexane	23
	Methylene chloride	714
	Xylene	645
	Water	.00012
63-9	Vapor Pressure	1.87 X 10 ⁻⁵ mm Hg at 25 °C 8.15 X 10 ⁻⁵ mm Hg at 35 °C
63-10	N/A	
63-11	Octanol/Water Partition Coefficient	91,000
63-12	N/A	
63-13	Stability	Stable under normal conditions
63-17	Storage Stability	Storage below 50 °C recommended
63-20	Corrosion	Slightly corrosive to stainless steel. Corrosive to copper and brass

RCB Comments:

The specific gravity or bulk density should be reported at 20 or 25 °C.

Conclusions and Recommendations:

1. With the exception of the bulk density that should be reported at 20 or 25 °C, the remaining product chemistry data requirements for chlorpyrifos (Dursban R), EPA Registration No. 464-558 have been satisfied.
2. We recommend that data available for Dursban R in this review, be added to the chlorpyrifos Registration Standard.
3. An updated copy of product chemistry Table B is attached.

Attachment 1: Table B (2 pages)

Attachment 2: Confidential Appendix (6 pages)

Page 1 : Confidential Statement of formula.

Page 2 : Beginning materials.

Pages 3-5 : Manufacturing process.

Page 6 : Certification of Limits

(Copies of Attachment 2 to: R.F., S. Malak, chlorpyrifos S.F.; chlorpyrifos Registration Standard File, TOX, EllenbergerPM #12-RD, and PMSD/ISS).

cc: Circu, EAB, EEB

RDI:P.Errico:August 26, 1985;R.D.Schmitt:August 26, 1985
TS-769:RCB:S.Malak:Typist:Rm.810:CM#2:Ext.557-7377:August 30, 1985

CHLOROPYRIFOS (DURESAN R)

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
CHLOROPYRIFOS (DURESAN R)
EPA REGISTRATION NO. 464-558

2.122.120 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required		Footnote Number
			Yes	No	
<u>Product Identity:</u>					
61-1 - Product Identity and Disclosure of Ingredients	MP	R	☐	☒	
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	☐	☒	
61-3 - Discussion of Formation of Impurities	MP	R	☐	☒	
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	MP	CR	☐	☒	
62-2 - Certification of Limits	MP	R	☐	☒	
62-3 - Analytical Methods to Verify Certified Limit	MP	R	☐	☒	
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	MP	R	☐	☒	
63-3 - Physical State	MP	R	☐	☒	
63-4 - Odor	MP	R	☐	☒	

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DATA REQUIREMENT FOOTNOTES:
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ATTACHMENT 1

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
EPA REGISTRATION NO. 464-564

Guideline Citations and Name of Test	Test Substance	Guidelines Status	Are Data Required		Footnote Number
			Yes	No	
129.120 - PESTICIDE CHEMISTRY (On't)					
<u>Physical and Chemical Characteristics</u> (Continued)					
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	☒	☐	1/ Should be reported at 20 or 25 °C.
63-12 - pH	MP	N/A	☐	☐	
63-14 - Oxidizing or Reducing Action	MP	N/A	☐	☐	
63-15 - Flammability	MP	N/A	☐	☐	
63-16 - Explosibility	MP	N/A	☐	☐	
63-17 - Storage Stability	MP	R	☐	☒	
63-18 - Viscosity	MP	N/A	☐	☐	
63-19 - Miscibility	MP	N/A	☐	☐	
63-20 - Corrosion Characteristics	MP	R	☐	☒	
<u>Other Requirements:</u>					
64-1 - Submittal of samples	MP	CR	☐	☐	
R = Required; CR = Conditionally Required; MP = Manufacturing-use Product					
<u>DATA REQUIREMENT FIGURES:</u>					

AD-RM-4524-95
Chlorpyrifos Review

Page 9 is not included in this copy.

Pages _____ through _____ are not included.

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 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.

AD-RM-4524-95

Chlorpyrifos Review

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Pages 10 through 14 are not included.

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 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.

Conf. Appendix

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