9-27-85
R.F.

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

SEP 27 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 464-474. Chlorpyrifos (Lorsban™ 1-2E/Polyethylene-D) Product Chemistry Follow-Ups in Response to the Chlorpyrifos Registration Standard Data Capr. Accession No. 257592. RCB No. 936.

FROM: Sami Malek, Ph.D., Chemist
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Amy S. Riopin, Chief
Science Integration Staff
Hazard Evaluation Division (TS-769)

and

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

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

In response to the chlorpyrifos Registration Standard of February 28, 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), Lorsban™ 1-2E/Polyethylene-D, EPA Reg. No. 464-474.

Chlorpyrifos is the common name for the insecticide O,O-diethyl O-(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.

794

15748 15749

Detailed data gaps cited in Table B of the Standard for MUP's 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 charateristics 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 Indentity and Disclosure of Ingredients

Dow's Response:

Lorsban* 1-PR/polythylene-D, EPA Registration No. 464-474, is a granular solid composed of polyethylene pellets impregnated with 10% chlorpyrifos O,O-diethyl O-(3,5,6-trichloro-2-pyridyl)phosphorothioate using [redacted] Lorsban* 1-PR/polyethylene-D is a manufacturing use product produced by Dow Chemical Company for export sale only for the purpose of manufacturing polyethylene shrouds for banana plants. A copy of the 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 one page, a copy of which is included on page 3 of the Confidential Appendix, Attachment 2 of this review.

795

(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 Impurities

Dow's Response:

Lorsban 1-PE/polyethylene-D, Registration No. 464-474 is a granular solid composed of polyethylene pellets impregnated with [redacted] chlorpyrifos, the source of which is [redacted] Therefore, we expect that the impurities in both technical products, [redacted] and Lorsban 1-PE/polyethylene-D to be identical. These impurities were reported by Dow under [redacted] Dow Company reported that since Lorsban 1-PE/polyethylene-D is manufactured by [redacted] no new impurities are introduced except for the inert ingredients, polyethylene pellets.

RCB Comments:

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

Series 62: Analysis of Certification of Product Ingredients

§62-1 Preliminary Analysis

Dow's Response:

The analysis included in this submission is for several randomly selected batches of the manufacturing-use product, Lorsban 1-PE/Polyethylene-D, sampled during four production periods in 1984. Samples were analyzed for chlorpyrifos per se using Dow's Method No. ML-AX-82-24(QA No. 1972) and TC-AX-82-14 (QA No. 1971). The resulting upper and lower limits for chlorpyrifos was reported at [redacted] respectively. The company did not report on any impurities associated with Lorsban 1-PE/ Polyethylene-D nor did they report on any intentionally added

ingredients. These data, however, were previously reported and discussed in connection with [redacted]

RCB Comments:

No additional information is required under §62-1.

§62-2 Certification of Limits

Dow's Response:

The manufacturer has given the upper and lower certification of limits for chlorpyrifos per se at [redacted] respectively. The upper and lower limits of the intentionally added ingredients were also reported by Dow Company as could be seen in page 3 of the Confidential Appendix, Attachment 2 of this review. The upper certified limits for the impurities associated with Lorsban 1-PE/Polyethylen-D/were not reported in this submission. These impurities, however, are the same as those in [redacted]

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 chlorpyrifos per se in the manufacturing use product, Polyethylene-D, is Dow's Method No. TC-AM-82-24 (QA No. 1972), entitled "Chlorpyrifos in Polyethylen-D [illegible] August, 1982". An identical method employed for chlorpyrifos determination in Lorsban 1-PE is Dow's method No. TC-AM-82-14(QA No. 1971), entitled "Chlorpyrifos in Lorsban 1-PE Insecticidal Granules, August, 1982". [redacted]

This represent a data gap.

Dow's method No. ML-AM-81 (CA No. 2349) is used for determination of the impurities in [redacted] which are the same as those in Polyethylene-D ([redacted] chlorpyrifos product chemistry day gaps).

RCB Comments

Validation data including actual sample values and representative chromatograms should be submitted. This data gap is not satisfied.

Series 63: Physical and Chemical Characteristics

Dow's Response:

The physical and chemical characteristics for the manufacturing use product, Lorsban 1-PS/Polyethylene D, required under this series, were reported as follows:

63-2	Color	Mixed White and Blue Pellets
63-3	Physical State	Granular Solid
63-4	Odor	Mercaptan
63-7	Specific Gravity	0.92 - 0.93
63-12	pH	NA
63-14	Oxidizing/Reducing	None
63-15	Flammability	NA
63-16	Explodability	None
63-17	Storage Stability	Stable under normal conditions Storage below 50 °C recommended
63-18	Viscosity	NA
63-19	Miscibility	NA
63-20	Corrosion	None

RCB Comments:

No additional information is required under series 63.

Conclusions and Recommendations:

1. With the exception of data including actual sample values and representative chromatograms, required under §62-3, product chemistry data requirements for chlorpyrifos (Lorsban 1-PE/Polyethylen-D), EPA Registration No. 464-474, have been satisfied.

2. We recommend that data available for Lorsban 1-PE/Polyethylene-D 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 (3 pages)
Page 1 : Confidential Statement of Formula.
Page 2 : Beginning materials.
Pages 3 : Manufacturing process and certified limits.
cc: with Attachment 2 to: R.F., S. Malek, chlorpyrifos Registration Standard File, SCK, Ellenberger(PM §12,22) and FHSD/ISB.

cc: Circu, PSB, RAB.
RDI:P.Errico:6/24/85:D.D.Schmitt:6/24/85
TS-769:PSB:S.Malek:mh:6/25/85:CM2:Ext.557-7377

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
Chlorpyrifos (Lorsban 4-EW/Polyethylene D) EPA Reg. No. 464-474

§158.150 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number
Product Identity (Continued)					
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	☐	☒	
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	CR	☐	☒	
62-2 - Certification of Limits	MP	R	☐	☒	
62-3 - Analytical Methods to Verify Certified Limit	MP	R	☒	☐	1/
Physical and Chemical Characteristics					
63-2 - Color	MP	R	☐	☒	
63-3 - Physical State	MP	R	☐	☒	
63-4 - Odor	MP	R	☐	☒	

1/ Actual sample values and representative chromatograms.

CHEMICAL NOMINEE Attachment 1
TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
Chlorpyrifos (Location 1-PS/Polyethylene B) EPA Reg. No. 464-474

§158.120 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test:	Test Substance	Guidelines Status	No Data Required Yes	No	Footnote Number
Physical and Chemical Characteristics (Continued)					
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	☐	☒	
63-12 - pH	MP	N/A	☐	☐	
63-14 - Oxidizing or Reducing Action	MP	CR	☐	☒	
63-15 - Flammability	MP	N/A	☐	☐	
63-16 - Explodibility	MP	R	☐	☒	
63-17 - Storage Stability	MP	R	☐	☒	
63-18 - Viscosity	MP	N/A	☐	☐	
63-19 - Miscibility	MP	N/A	☐	☐	
63-20 - Corrosion Characteristics	MP	R	☐	☒	
Other Requirements:					
66-1 - Submittal of samples	MP	CR	☐	☐	

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

EPA REFERENCE DOCUMENTS:

AQ-RTN-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.

AR-RTN-4524-95

Chlorpyrifos Review

Page____ is not included in this copy.

Pages 10 through 11 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

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.
