



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

R.F.

9-11-85

SEP 11 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration Nos. 432-625 and 432-662. Chlorpyrifos (Ultratec®) Product Chemistry Data Follow-up in response to the Chlorpyrifos Registration Standard. Accession No.s 257061 and 257122. RCB No's 745 and 765.

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

TO: Amy S. Rispin, 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 *R P Schmitt*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769) *for*

In response to the chlorpyrifos Registration Standard of February 29, 1984, Penick Corporation responded on March 5, 1985, by submitting product chemistry data cited in the Standard as data gaps for their products Ultratec® (Reg. Nos. 432-625 and 432-662). Both products are identical in every respect except that #432-662 is sold for "repackaging", whereas #432-625 is formulated for ready to use and may be regarded as an end-use product.

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. [REDACTED] apparently sells technical chlorpyrifos to several other companies for formulating intermediate products or manufacturing-use products (MUP), several of which are registered with the EPA. Penick

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

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Corporation is one of these companies that formulates Ultratec® which contains 25 percent technical chlorpyrifos (Reg. Nos. 432-625 and 432-662).

Detailed data gaps cited in table B of the Standard, for manufacturing-use products, 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 manufacturing-use and end-use products. Data under Series 63 are now being addressed by the Residue Chemistry Branch.

In our discussion below, we will list the data gaps in the product chemistry requirements of Part III, (§158.120, FR 47 53192, November 24, 1982), followed by Penick's response and our comments.

Series 61: Product Identity and Composition

§61-1 Product Identity and disclosure of ingredients

Penick's Response:

Ultratec® insecticides (EPA Reg. Nos. 432-625 and 432-662) are transparent emulsions containing 25 percent chlorpyrifos. They are manufactured by Penick Corporation for sale and distribution to formulators for repacking or direct use. Copies of the Confidential Statement of Formula's are included in pages 1 & 2 in the Confidential Appendix, Attachment 2 of this review.

RCS Comments

No additional information is required under §61-1.

§61-2 Description of beginning materials and manufacturing process

- (a) Beginning materials: are reported by Penick in one page, a copy of which is included in page 3 of the Confidential Appendix, Attachment 2 of this review. All the inerts of the Ultratec® formulations are included.
- (b) Manufacturing process: is reported by Penick in one page, a copy of which is included in page 4 of the Confidential Appendix, Attachment 2 of this review.
- (c) No changes in the beginning materials or manufacturing process are reported.

RCB Comments

Penick Corporation complied with all the data requirements under §61-2 of the Product Chemistry Guidelines, Subdivision D.

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

Ultratec® insecticides containing 25 percent chlorpyrifos are formulated by Penick Corporation for distribution to formulators for repackaging (§432-662) or for direct use (§432-625). The active ingredient is purchased from

Penick Corporation reported that no impurities are added, nor are they produced in the manufacturing, packaging or storage of Ultratec.

RCB Comments

Penick Corporation complied with data requirements under §61-3.

Series 62: Analysis of Certification of Product Ingredients§62-1 Preliminary Analysis

The analysis included in this submission is for five randomly selected production batches of Ultratec® sampled during 1984. Samples were analyzed for chlorpyrifos *per se* with a resulting upper and lower limits of [redacted] percent, respectively. The company did not report on any impurities associated with Ultratec, nor did they report on any intentionally added ingredients in technical chlorpyrifos. These data, however, were previously reported as discussed in this review in connection with §61-3.

RCB Comments

No additional information is required under §62-1.

\$62-2 Certification of LimitsPenick's Response:

The manufacturer has given the upper and lower certification of limits for the purity of technical chlorpyrifos as well as intentionally added ingredients in Ultratec. A copy of the registrant's one page report is included in page 5 of the Confidential Appendix, Attachment 2 of this review.

RCB Comments

No additional information is required under \$62-2.

\$62-3 Analytical Methods for Enforcement of LimitsPenick's Response:

The analytical method employed for the determination of chlorpyrifos per se in UltraTec is described in this submission under the title "Determination of 25 percent Dursban and 5 percent Allethrin in Emulsifiable Concentrate."

Sample chromatograms are included. No validation data have been submitted by Penick Corporation.

RCB Response

Validation data are needed for the analytical method described for chlorpyrifos determination in UltraTec.

Series 63: Physical and Chemical CharacteristicsPenick's Response:

The physical and chemical characteristics for the Ultratec, required under this series were reported as follows:

- \$63-2 Color - clear to hazy brown.
- \$63-3 Physical state - liquid
- \$63-4 Odor - fatty and mercaptan-like.
- \$63-7 Density, bulk density or specific gravity - 8.49 to 8.74 lb/gal, or 1.02 to 1.05 g/ml.
- \$63-12 pH - 1 percent w/w aqueous solution - 4.0
- \$63-14 Oxidizing/reducing reaction - no reaction.
- \$63-15 Flammability/Flame Extension Flash Point 60 °F (15.5 °C) min.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

- §63-16 Explodability - None.
 §63-17 Storage Stability - Stable for 96 days in an oven at 40 °C.
 §63-18 Viscosity - 43 cps at 25 °C - spindle 1; 50 rpm; Brookfield Model RTU.
 §63-19 Miscibility - water, acetone, alcohol.
 §63-20 Corrosion characteristics - None.

RCB Comments

No additional information is required under Series 63.

Conclusions and Recommendations

1. Product Chemistry data gaps remaining comprise validation data for the analytical method described for chlorpyrifos determination in UltraTec.
2. We recommend that data for Ultratec® (Reg. Nos. 432-625 and 432-662) data 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 (5 pages)

pp. 1 & 2: Confidential Statement of Formulas

P. 3 : Beginning materials

P. 4 : Manufacturing process

P. 5 : Certification of limits

(Copie of Attachment 2 to : R.F., S. Malak, chlorpyrifos S.P., chlorpyrifos Registration Standard File, TOX, Ellenberger-PM #12-RD, and FMSD/ISR).

cc: Circu, EEB, EAB

RDI: P. Errico; 8/9/85; R. D. Schmitt; 8/22/85

TS-769: RCB: S. Malak; TAR:RM 810:CM#2:X557-7377;8/30/85.

CHEMISTRY REQUIREMENTS

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLORPYRIFOS (ULTIMATE)
EPA REG. NO.'S 432-625
and 432-662

§150.120 - PRODUCT CHEMISTRYGuideline Cite and
Name of TestTest
SubstanceGuidelines
StatusAre Data a
Required
Yes NoFootnote
NumberProduct Identity: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

☐☒Validation Requirements:

Validation data for the analytical method.

Guideline Requirements

TABLE 3
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLOROPYRIFOS (ULTRATEC)
EPA REG. NO.'s 432-625
and 432-662

5152.120 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data ^a Required		Footnote Number
			Yes	No	
<u>Physical and Chemical Characteristics</u> (Continued)					
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	☐	☒	
63-12 - pH	MP	CR	☐	☒	
63-14 - Oxidizing or Reducing Action	MP	CR	☐	☒	
63-15 - Flammability	MP	CR	☐	☒	
63-16 - Explodability	MP	R	☐	☒	
63-17 - Storage Stability	MP	R	☐	☒	
63-18 - Viscosity	MP	CR	☐	☒	
63-19 - Miscibility	MP	CR	☐	☒	
63-20 - Corrosion Characteristics	MP	R	☐	☒	
<u>Other Requirements:</u>					
61-1 - Submittal of samples	MP	CR	☐	☐	

Required; CR = Conditionally Required; MP = Manufacturing-use Product
A REQUIREMENT FOOTNOTE:

HQ-RM-4524-95
Chlorpyrifos Review

Page is not included in this copy.

Pages 8 through 9 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.

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Chlorpyrifos Review

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Pages 10 through 12 are not included.

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Conf. Appendix

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