

US EPA ARCHIVE DOCUMENT

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

SEP 25 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 464-559. Chlorpyrifos (Dursban 30 SEC Insecticidal Concentrate®) Product Chemistry Follow-Ups in Response to the Chlorpyrifos Registration Standard Data Gaps (Accession No. 257595). RCB No. 940.

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-Resistant Branch
Registration Division (TS-757)

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

In response to the Chlorpyrifos Registration Standard of February 29, 1984, Dow Chemical Company responded on April 6, 1985, by submitting product chemistry data cited in the Standard as data gaps for their manufacturing-use Product (MUP), Dursban 30 SEC Insecticidal Concentrate®.

Chlorpyrifos is the common name for the insecticide O,O-diethyl O-(1,3,6-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, Pesticide Registration; Data Requirements for Pesticide Registration, Final Rule (40 CFR Part 158, 49 FR 42656, 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 30 SEC Insecticidal Concentrate[®], EPA Reg. No. 464-559, is a solution of [REDACTED] in a formulation containing a minimum assay of 30% chlorpyrifos 10,0-diethyl (3,5,6-trichloro-2-pyridyl)phosphorothioate]. Dursban 30 SEC is a manufacturing-use product, produced by Dow Chemical Company that may be used for formulation of other manufacturing-use products or end-use products. A copy of the on page Confidential Statement of Formula is included in p. 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: reported by Dow in one page, a copy of which is attached in p. 2 of the Confidential Appendix, Attachment 2 of this review.
- b. Manufacturing process: reported by Dow in one page, a copy of which is attached in p. 3 of the Confidential Appendix, Attachment 2 of this review.
- c. Changes in beginning materials or manufacturing process: No changes in the beginning materials or manufacturing process were reported.

RCB Comments

Dow 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 30 SEC Insecticidal Concentrate is a manufacturing-use product containing 30% chlorpyrifos, Reg. No. 464-559. It is formulated by Dow Company by dilution of their manufacturing-use product, [REDACTED]

[REDACTED] (see page 3 of the Confidential Appendix, Attachment 2 of this review). Therefore, the nature of the impurities in both manufacturing-use product [REDACTED] and Dursban 30 SEC, is expected to be identical. These impurities were reported by Dow under [REDACTED]

[REDACTED] product chemistry data gaps. Dow Company reported that since Dursban 30 SEC is a [REDACTED] no new impurities are introduced from the active ingredients. (see page 3 of the Confidential Appendix, Attachment 2.)

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 five randomly selected production batches of the manufacturing-use product, Dursban 30 SEC, sampled during 1981. Samples were analyzed for chlorpyrifos per se using Dow's method No. 26054 (QA No. 1666) with a resulting upper and lower limits of [REDACTED] respectively. The analysis included determination of the inerts with a resulting upper and lower limits as shown on page 3 of the Confidential Appendix, Attachment 2 of this review.

Data on intentionally added ingredients were previously discussed by S. Malak in connection with [REDACTED]

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

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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 as well as the upper limit of the inerts associated with [redacted] which are the same as those in Dursban 30 SEC (Reg. No. 464-559), were all reported by Dow Company as could be seen on page 3 of the Confidential Appendix, Attachment 2 of this review).

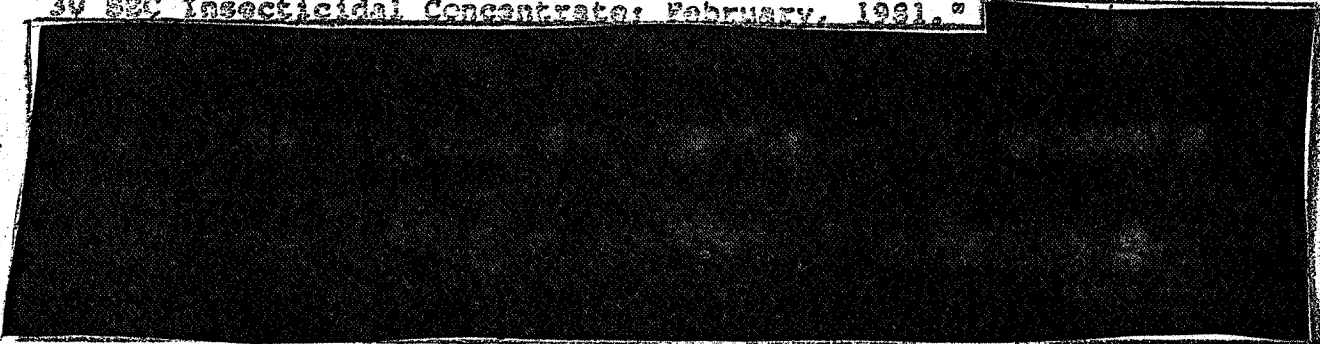
RCB Comments

No additional information is required under §62-2.

§62-3 Analytical Methods for Enforcement of Limits

Dow's Response

The analytical method employed for the determination of chlorpyrifos per se in the manufacturing-use product, Dursban 30 SEC is Dow's method No. 26054 (QA No. 1666), entitled "Dursban 30 SEC Insecticidal Concentrate; February, 1961."



Dow's method No. HL-AH-81 (QA No. 2349) is used for determination of the impurities in [redacted] which are the same as those in [redacted] and 30 SEC.

RCB Comments

No additional information is needed under §62-3.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

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Series 63: Physical and Chemical CharacteristicsDow's Response

The physical and chemical characteristics for the manufacturing-use product, Dursban 30 SEC, required under this series were reported as follows:

63-2	Color	Amber
63-3	Physical State	Liquid
63-4	Odor	Mild aromatic
63-7	Specific Gravity	1.09
63-12	pH	4.6
63-14	Oxidizing/Reducing	N/A
63-15	Flashpoint	129 °F
63-16	Explosibility	N/A
63-17	Storage Stability	2 years at 25 °C
63-18	Viscosity	87 cps at 20 °C
63-19	Miscibility	Not miscible with oils
63-20	Corrosion	Noncorrosive to stainless steel Corrosive to copper and brass

RCB Comments

No additional information is required under section 63.

Conclusions and Recommendations

1. Product chemistry data requirements for chlorpyrifos (Dursban 30 SEC), EPA Reg. No. 464-559 have been satisfied.
2. We recommend that data available for Dursban 30 SEC in this review, be added to the Chlorpyrifos Registration Standard.
3. An updated copy of product chemistry table B is included as Attachment 1.

Attachment-1: Table B (2-pages)

Attachment-2: Confidential Appendix (4-pages)

P. 1: Confidential Statement of Formula

P. 2: Beginning materials

P. 3,6: Manufacturing process p.4: certified limits.

ccw/copies of Attachment 2 to: R.F., S. Malak, chlorpyrifos

S.F., chlorpyrifos Reg. Std. File, TOX, Ellenberger-PM #13-

DD, and PHSD/ISS (Sited by:wh:9/20/05

cc: R.F., Circu, Reviewer, Subject File, Amended Use File, PHSD/ISS

PHS:Section Head:P.V. SRESCD:Date:9/12/05:RDSchmitt:Date:9/12/05

25-769:Reviewer Initials (S.Malak:PM: 810:557-7277:CM02

REVIEWER CONTACT FIDING:DATE:9/17/05:PHONE NUMBER:608-1278

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CRIBSIX MANUFACTURING

Attachment 1

TABLE 7

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CRIBSIX:

SUB-100 - PINKIE CHEWERY

Crabapple Citric Acid and
Van of Test

Footnote
Number

Are Data
Required
Yes No

Outlines
Status

Test
Substance

Product Identifiers
(Optional)

61-1 - Product Identity and Disclosure
of Ingredients

Yes No

R

61-2 - Description of Beginning Materials
and Manufacturing process

Yes No

R

61-3 - Discussion of Formation of
Impurities

Yes No

R

Analysis and Certification of Product
Ingredients

62-1 - Preliminary Analysis

Yes No

CR

62-2 - Certification of Limits

Yes No

R

62-3 - Analytical Methods to Verify
Certified Limit

Yes No

R

Physical and Chemical Characteristics

63-2 - Color

Yes No

R

63-3 - Physical State

Yes No

R

63-4 - Odor

Yes No

R

CHEMISTRY REQUIREMENTS Attachment 1
TABLE B

MINIMUM SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICALS:

929.120 - YOGURT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required	Footnote Number
			Yes No	
69-7 - Acidity, milk tonality, or specific gravity	RP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	
69-12 - pH	RP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
69-13 - Gelling or Reducing Action	RP	NA	<input type="checkbox"/> <input type="checkbox"/>	
69-15 - Stabilitas	RP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
69-16 - Replacability	RP	NA	<input type="checkbox"/> <input type="checkbox"/>	
69-17 - Storage Stability	RP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	
69-18 - Viscosity	RP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
69-19 - Miscibility	RP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
69-20 - Curdion Characteristics	RP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	

Other Requirements:

69-1 - Minimal of samples

Required; CR = Conditionally Required; RP = Manufacturer In-house Product
MINIMUM REQUIREMENTS

HO-RM-4524-95

Chlorpyrifos Review

Page 8 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-RIN-4524-95

Chlorpyrifos Review

Page _____ is not included in this copy.

Pages 9 through 11 are not included.

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Conf. Appendix

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