

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: Chlorpyrifos; Response to data gaps in product chemistry.
EPA Reg. No. 45606-2 through 45606-9
Accession No. 257470
RCB Nos: 869, 870, 871, 872, 873, 874, 875, 876

FROM: Gobind Makhijani and Karl Arne, Chemists
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THRU: Charles L. Trichilo, Chief
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TO: Amy Rispin, Chief
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and

Jay Ellenberger
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Registration Division (TS-767C)

Insecta Paint Inc. has submitted data intended to satisfy product chemistry data gaps that were uncovered in the Chlorpyrifos Registration Standard. Eight manufacturing use products, tradenamed Insecta 101, Insecta 102, etc, thru Insecta 108, are involved. These products are very similar in composition; the percent a.i. varies from 36.0 to 44.6%. The different formulations are designed to adapt to the formulas of different paint manufacturers.

Below are the requirements of the Product Chemistry Guidelines, followed by Insecta's response and RCB's comments.

Series 61: Product Identity and Composition.

601-1 Product Identity and Disclosure of Ingredients

Insecta's Response:

For each manufacturing use product (MUP), the registrant has submitted a statement of composition. However, these statements are different than those on file at EPA. When asked about this

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discrepancy, Insecta sent additional data (letter of 5/17/85, P. Quinlan, Insecta, to J. Ellenberger, RD). Details of Insecta's submission and letter are given in the Confidential Appendix, page one.

RCB's Comment:

RCB presumes that the originally submitted data on the composition of Insecta's products is incorrect and that the more recent letter is correct. However, the data presented in the letter are not complete. The registrant should submit statements of formula for each formulation that include:

- (1) The name, nominal concentration, and certified limits for each active ingredient and each intentionally-added inert ingredient.
- (2) The name and upper certified limit for each impurity or each group of impurities for which a certified limit is required (see § 62-2).
- (3) The purpose of each active ingredient and each intentionally-added inert ingredient.
- (4) For each ingredient required to be listed by paragraph (1) the chemical name from the Chemical Abstracts Index of Nomenclature or other well-defined name, and the Chemical Abstracts Service (CAS) Registry Number.

These data are available for some, but not all, of the ingredients in Insecta's product. See the Confidential Appendix for details.

§61-2 Description of Beginning Materials and Manufacturing Process.

Insecta's Response:

See the Confidential Appendix.

RCB's Comment:

Additional information is required. See the Confidential Appendix.

§61-3 Discussion of Formation of Impurities

Insecta's Response:

No additional impurities are formed besides those present in the technical and in the solvent used. The chlorpyrifos

A copy of ingredient limits and

impurities for [REDACTED]

The solvent used by Insecta Paint, Inc is discussed in Attachment 2, Confidential Appendix.

RCB's Comment:

No additional information is required under §61-3

§62-1 Preliminary Analysis

Insecta's Response:

The concentrations of active ingredient in the various formulations range from 44.62% for Insecta 101 and decrease in concentration to 38.0% for Insecta 108.

The registrant has submitted analysis for 6 batches of Insecta 101, prepared to contain 44.62% by weight of chlorpyrifos. Batch #1 was analyzed 10 times, while other batches were analyzed in duplicate. The standard deviation is 1.05 with confidence limits of 95%.

The registrant has stated that similar results are obtained for each of the other insecta concentrates.

RCB's Comment:

No further information is required under §62-1.

§62-2 Certification of Limits

Insecta's Response:

Based on the result of their analyses of six batches of Insecta 101, the registrant claims limits of [REDACTED] (see §62-1).

RCB's Comment:

Additional data are required:

The petitioner should certify a range for the active ingredient and each intentionally added inert ingredient. Presumably, for the active ingredient these numbers would be arrived at by adding and subtracting 1.05% from the percentages submitted with the confidential statement of formula. However, it isn't clear that the registrant wishes to calculate confidential limits for the inert ingredients in the same manner as for the active ingredient. Therefore, for the active ingredient and each intentionally added inert ingredient the registrant should, for each formulation, provide a certified limit in terms of a range.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

§62.3 Analytical Methods to Verify Certified Limits

Insecta's Response:

The registrant has furnished following methods for the determination of active ingredients in MUP's.

- (a) TLC method (Smith and Fischer - J. Agr. Food Chem. 15:1-p 182-6).

This is a quantitative method and cannot be used for quantitative purposes.

- (b) Stannous Chloride Method (APHA Method 424E).

RCB's Comment:

RCB considers the stannous chloride method to be adequate for enforcement of the certified limits. Validation data are available for Insecta 101 only, but considering the similarity of these formulations, no additional validation data are required.

No further information is required under §62-3.

Series 63: Physical and Chemical Characteristics

Insecta's Response:

See confidential appendix.

RCB's Comments:

No additional information is required under §63.

Attachment I: Table B (2 pages)

Copies to: Chlorpyrifos Registration Standard, SP, Reviewer, PMSD/ISB,
J. Ellenberger, PM # 12, RF, circ.

Attachment II: Confidential Appendix (4 pages)

Copies to: Chlorpyrifos Registration Standard, PMSD/ISB, Reviewers,
J. Ellenberger, PM # 12

CC: Chlorpyrifos Registration Standard, RF, Reviewer, PMSD/ISB, SP
J. Ellenberger, PM # 12

BDI: PEV, 9/27/85; RDS, 9/27/85

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QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

10-1-1968

10-1-1968

TABLE 3

MINOR SELECTIVE DATA REQUIREMENTS FOR MANUFACTURING UNIT PRODUCTS CONTAINING CHEMICAL: CHLORPYRIFOS
RAC NO 45600-2 THROUGH 45600-9

10-1-1968 - MAJOR COMPANY

Guideline Citation and
Date of Test

Test
Substance

Guideline
Status

Int Data
Required
Yes No

Footnote
Number

Product Identifiers

1-1 - Product Identity and Disclosure
of Ingredients

MP

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☐

1-2 - Description of Degrading Materials
and Manufacturing Process

MP

R

☒

☐

1-3 - Description of Formation of Impurities
Impurities

MP

R

☐

☒

Analysis and Certification of Product
Substance

1-1 - Preliminary Analysis

MP

CR

☐

☒

1-2 - Certification of Limits

MP

R

☒

☐

1-3 - Analytical Methods to Verify
Certified Limit

MP

R

☐

☒

Physical and Chemical Characteristics

1-1 - Color

MP

R

☐

☒

Not at this time

1-2 - Physical State

MP

R

☐

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1-3 - pH

MP

R

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10-1-1968 - MAJOR COMPANY

TABLE D
MANUFACTURING-USE PRODUCTS CONTAINING CHEMICALS: CHEMICALS
(SECTION 101 THROUGH 103)

101-103 - CHEMICALS

Chemical Name and Use of Use	Chemical Substance	Guidelines Status	Are Data Required	Footnote Number
101 - Density, Bulk Density, or Specific Gravity	NP	R	☐	☒
102 - pH	NP	CR	☐	☒
103 - Volatility or Volatile Fraction	NP	R	☐	☒
104 - Flammability	NP	CR	☐	☒
105 - Explosibility	NP	R	☐	☒
106 - Storage Stability	NP	R	☐	☒
107 - Viscosity	NP	CR	☐	☒
108 - Alkalinity	NP	CR	☐	☒
109 - Corrosion Characteristics	NP	R	☐	☒
110 - Volatility of Sample	NP	CR	☐	☐

Legend: CR - Conditionally Required, NP - Manufacturing-Use Product.
 NA - Not Applicable

HQ-RM-4524-95
Chlorpyrifos Review

Page is not included in this copy.

Pages 7 through 10 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.