

US EPA ARCHIVE DOCUMENT

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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:** *P. P. J.* Gobind Makhijani and Karl Arne, Chemists  
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Hazard Evaluation Division (TS-769C)

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

**TO:** Amy Rispin, Chief  
Science Integration Staff  
Hazard Evaluation Division (TS-769C)

and

Jay Ellenberger  
Product Team No. 12  
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, trademarked 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

*NO*

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MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED  
INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

discrepancy, Insecta sent additional data (letter of 5/17/85, P. Quinian, 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:i-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, FMSD/ISB, J. Ellenberger, PM # 12, RF, circ.

Attachment II: Confidential Appendix (4 pages)

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

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

SDI: FEV, 9/27/85; RDS, 9/27/85

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QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

TABLE 3

INDUSTRY SELECTIVE DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CESICAL: CHLORPYRIFOS

REG NO 45600-2 THROUGH 45600-9

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INDUSTRY SELECTIVE DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CESICAL: CHLORPYRIFOS  
REG NO 45600-2 THROUGH 45600-9

TABLE 3 - INDUSTRY SELECTIVE DATA REQUIREMENTS

Regulation Citation and Part of Table	Test Substance	Guideline Status	Int. Data Required		Footnote Number
			Yes	No	
1-1 - Label: Identity and Disclosure of Ingredients	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1-2 - Description of Degrading Materials and Manufacturing Process	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1-3 - Description of Reaction of Degradation Impurities	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
2-1 - Preliminary Analysis	MP	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
2-2 - Certification of Limits	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	For each HUP
2-3 - Analytical Methods to Verify Certified Limit	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3-1 - Color	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Not at this time
3-2 - Physical State	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3-3 - Color	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

TABLE 3 - INDUSTRY SELECTIVE DATA REQUIREMENTS

**TABLE B**  
**MANUFACTURING-INS PRODUCTS CONTAINING CHELATE CATALYSTS**  
**(EXCEPT FOR NUMBER 100)**

Alkylate Class and No. of Sulf.	Test Substance	Guidelines Status	Are Data Required	Footnote Number
			Yes No	
3-2 - Density, Salt Tendency, or Specific Gravity	MP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-23 - PI	MP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-24 - Coating or Viscosity Index	MP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-25 - Oxidability	MP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-26 - Stability	MP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-27 - Storage Stability	MP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-28 - Viscosity	MP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-29 - Stability	MP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-30 - Corrosion Characteristics	MP	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	
3-31 - Initial of Sample	MP	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	

Legend: CR - Critically Required, R - Manufacturing-Ins Product.

NO-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.