FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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CONFIDENTIAL

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: PCNB Product Chemistry and Residue Chemistry Registration Standard Update.

From: Richard D. Schmitt, Ph.D., Chief
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To: Lois Rossi, Chief
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and

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Attached are updates to the Product and Residue Chemistry Chapters of the PCNB Registration Standard prepared by Dynamac Corporation under supervision of the Dietary Exposure Branch, HED. They have undergone secondary review in the Dietary Exposure Branch and have been revised to reflect the Branch policies. The Guidance Document was published in January, 1987.

Attached are updated generic and product specific data requirement tables for the technical grade of the active ingredient and manufacturing-use products of PCNB. Also, an updated Residue Chemistry data requirements table has been attached.

If you need additional input please advise.

Attachment 1: PCNB Product Chemistry Registration Standard Update
Attachment 2: PCNB Residue Chemistry Registration Standard Update

cc (with attachments 1, and 2): E. Haeberer, PCNB Registration Standard File, PCNB Subject File, C. Furlow (PIB/FOD), J. Burrell (PIB/FOD), W. Boodee (HED), Dynamac

cc (without attachments): RF, Circ.(8), M. Hawkins (HED), P. Fenner-Crisp (HED)

DYNAMAC
CORPORATION

Final Report

PCNB
Task 4. Product Chemistry. Registration Standard Update

APRIL 25, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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PENTACHLORONITROBENZENE (PCNB)

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK - 4

INTRODUCTION

A Product Search Listing (PRD-2B4C) conducted 2/10/89 identifies the pentachloronitrobenzene (PCNB) manufacturing-use products (MPs) listed below in Table 1.

Table 1. PCNB manufacturing-use products.

Registrant	Formulation[a]	EPA Reg. No.
Uniroyal Chemical Company	99% T	400-401
	90% FI	400-414
Amvac Chemical Corporation	95% T	5481-197
Gustafson, Inc.	80% FI	7501-45
Prochimie International	97% T	8236-8[b]
Quimica Organica de Mexico	96% T	10820-1

[a] FI = formulation intermediate
T = technical

[b] transferred from Aceto 97% T (EPA Reg. No. 2749-9)

The PCNB Guidance Document dated 1/87 requires updated data on all product chemistry topics for each of the registered MPs listed above. In response to the Guidance Document, Uniroyal (1987; MRID 40287901 and 1988; MRID 40506101) submitted product chemistry data for the 90% T (EPA Reg. No. 400-414) and Amvac (1988; MRIDs 40668601 and 40668602) submitted product chemistry data for the 95% T (EPA Reg. No. 5481-197). These data are reviewed and evaluated below.

Quimica Organica de Mexico responded to the Guidance Document (1986; MRIDs 40066901 and 40066902) for their 96% T (EPA Reg. No. 10820-1); these data have been reviewed by the Agency. Uniroyal and Quimica subsequently entered into an agreement whereby the latter would provide generic product chemistry data for Guidelines Reference Nos. 61-1, -2, and -3; 62-1, -2, and -3; and 63-2 through -14 for the technical grade of the active ingredient (TGAI) of PCNB (F. Griffith, DEB No. 2781; dated 11/16/87). We note, however, product chemistry data requirements apply to <u>each individual pesticide product</u>, and that certain data may be shared between two products only if it can be shown that their chemical compositions are the same. Therefore, separate data are required for each Quimica and Uniroyal product. Quimica submitted additional data for the 96% T (1987; MRIDs 40414901, 40414902,

and 40334601) in response to Agency-noted deficiencies; however, in 1988, Quimica applied for a pesticide registration amendment to increase the concentration of PCNB in this product and additional data in support of the increase were submitted (N. Gray, DEB 3880; dated 8/19/88). Therefore, the data in MRIDs 40414901, 40414902 and 40334601 are outdated and not reviewed in this update. In support of the amended concentration, Quimica submitted new product chemistry data (1988; MRIDs 40609601, 40609602, and 40609603) for the 96% T (EPA Reg. No. 10820-1); these new submissions were reviewed by the Agency.

No information has been submitted by Gustafson, Inc. for the 80% FI (EPA Reg. No. 7501-45), or by Prochimie International for the 97% T (EPA Reg. Nos. 8236-8).

Corresponding to each of the Topical Discussions listed below are the Guideline Reference Numbers from "Pesticide Assessment Guidelines - Subdivision D - Product Chemistry," referred to in Title 40 of the Code of Federal Regulations (40 CFR), Part 158, "Data Requirements for Registration," Subpart C, "Product Chemistry Data Requirements." These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of pentachloronitrobenzene.

	Guidelines Reference No. from 40 CFR §158.155-190
Product Composition and Manufacture	61-(1-3)
Analysis and Certification of Product Ingredients .	62-(1-3)
Physical and Chemical Characteristics	63-(2-20)

SUMMARY

The following Product Chemistry data are required:

- All generic and product specific data for the Prochimie, International 97% T (EPA Reg. No. 8236-8) and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45).
- For the Uniroyal Chemical Co. 99% T (EPA Reg. No. 400-401), data concerning the beginning materials and manufacturing process, formation of impurities, preliminary analysis, enforcement analytical methods, and physical/chemical properties.
- For the Uniroyal Chemical Co. 90% FI (EPA Reg. No. 400-414), data concerning product identity and disclosure of ingredients, beginning materials and manufacturing process, certified limits, enforcement analytical methods, and physical/chemical properties.

- For the Quimica Organica 96% T (EPA Reg. No. 10820-1), data concerning the beginning materials and manufacturing process.

- For the Amvac Corp. 95% T (EPA Reg. No. 5481-197), data concerning the beginning materials and manufacturing process, preliminary analysis, enforcement analytical methods, and physical/chemical properties.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

The PCNB Guidance Document requires all product specific data pertaining to product identity and disclosure of ingredients.

In response to the Guidance Document, Amvac Chemical Corporation (1988; MRIDs 40668601 and 40668602) submitted product identity information and disclosure of ingredients for the 95% T (EPA Reg No. 5481-197). These data, reviewed in Confidential Appendix A, satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition for the Amvac 95% T (EPA Reg No. 5481-197). No additional data are required.

In support of the amended registration to increase concentration and in response to the Guidance Document requirements, Quimica Organica de Mexico (1988; MRIDs 40609601 and 40609602) submitted product identity information and disclosure of ingredients for the 96% T (EPA Reg. No. 10820-1). These submissions have been reviewed by N. Gray (DEB No. 3880; dated 8/19/88) and found to satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition for the 96% T (EPA Reg. No. 10820-1). No additional data are required.

Uniroyal Chemical Company (1987; MRIDs 40287901 and 40506101) submitted product composition data in response to the Guidance Document for the 90% FI (EPA Reg No. 400-414). These data, reviewed in Confidential Appendix A, do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition for Uniroyal 90% FI (EPA Reg No. 400-414) because the nominal concentration, CAS Registry Numbers, and EPA Registration Number of the source product (active ingredient), and the nominal concentration and purpose of the inert ingredient were not submitted. Additional data are required.

Uniroyal submitted a CSF for the 99% T (EPA Reg. No. 400-401). These data are presented in Confidential Appendix A and satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-

1) regarding product composition for the Uniroyal 99% T (EPA Reg No. 400-401). No additional data are required.

No product identity and composition data have been submitted in response to the Guidance Document for the Gustafson 80% FI (EPA Reg. No. 7501-45), and Prochimie International 97% T (EPA Reg. No. 8236-8). The Guidance Document requirements for these products remain outstanding.

61-2. Description of Beginning Materials and Manufacturing Process

The PCNB Guidance Document dated 1/87 requires all generic and product-specific data regarding starting materials and the manufacturing/formulation process for all registered MPs. The Guidance Document also specifies that the registrants are required to submit annual progress reports summarizing efforts to implement measures to reduce levels of hexachlorobenzene (HCB) in the TGAI to <0.1%.

In response to the Guidance Document, Amvac Chemical Corporation (1988; MRID 40668601) submitted data pertaining to the starting materials and manufacturing process of the 95% T (EPA Reg. No. 5481-197). The registrant has also included in the submission the names and addresses of the suppliers of the starting materials along with their specifications. A discussion of the current manufacturing process, including purification procedures to reduce the concentration of HCB to <0.1% by weight of the TGAI, is summarized in Confidential Appendix B. These data do not satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the production process respectively for the Amvac 95% T (EPA Reg. No. 5481-197) because the relative percentages of beginning materials, the temperatures and pH values at various stages in the manufacturing process, the time required for the reaction and purification steps, and descriptions of quality control procedures employed during production were not submitted. Additional data are required.

In support of the amended registration to increase concentration and to fulfill Guidance Document requirements, Quimica Organica de Mexico (1988; MRIDs 40609601 and 40609602) submitted information pertaining to the starting materials and manufacturing process for the 96% T (EPA Reg. No. 10820-1). This submission has been reviewed by N. Gray (DEB No. 3880 dated 8/19/88) and found not to satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the production process respectively for 96% T (EPA Reg. No. 10820-1) because although the registrant has provided adequate data to indicate that a purer TGAI is being produced containing <0.1% HCB, an explanation is needed regarding

any changes, if any, that have been made in the manufacturing process of crude PCNB since the submissions dated 4/28/83 and 11/7/85. Additional data are required.

Uniroyal Chemical Company (1987; MRID 40287901) submitted data in response to the Guidance Document pertaining to starting materials and the formulation process for the 90% FI (EPA Reg No. 400-414). The registrant submitted the name and address of the supplier of the inert starting material along with the specifications. A description of the formulation process appears in Confidential Appendix B. These data do not satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the production process respectively for the Uniroyal 90% FI (EPA Reg. No. 400-414) because the source of the technical was not identified. Additional data are required.

No data pertaining to the starting materials and manufacturing process have been submitted in response to the Guidance Document for the Uniroyal 99% T (EPA Reg. No. 400-401), the Gustafson 80% FI (EPA Reg. No. 7501-45), or the Prochimie International 97% T (EPA Reg. No. 8236-8). Guidance Document requirements for these products still are outstanding.

61-3. Discussion of the Formation of Impurities

The Guidance Document dated 1/87 requires generic and product-specific data regarding the formation of impurities. The Guidance Document also specifies that the registrants are required to submit annual progress reports summarizing efforts to implement measures to reduce levels of hexachlorobenzene (HCB) in the TGAI.

Amvac Chemical Corporation (1988; MRID 40668601) submitted a theoretical discussion of the formation of impurities in response to the Guidance Document for the 95% T (EPA Reg. No. 5481-197). The discussion, presented in Confidential Appendix C, satisfies requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the 95% T (EPA Reg. No. 5481-197). No additional data are required.

In support of the amended registration to increase concentration and in response to Guidance Document requirements, Quimica Organica de Mexico (1988; MRIDs 40609601 and 40609602) submitted discussions of the formation of impurities for the 96% T (EPA Reg. No. 10820-1). This information was reviewed and accepted by N. Gray (DEB No. 3880; dated 8/19/88) to satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the 96% T (EPA Reg. No. 10820-1). No additional data are required.

Uniroyal Chemical Company (1987; MRID 40287901) submitted a brief discussion of the formation of impurities in response to the Guidance Document for the 90% FI (EPA Reg No. 400-414). The discussion, presented in Confidential Appendix C, satisfies 40 CFR §158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the 90% FI (EPA Reg No. 400-414). No additional data are required.

No information pertaining to the discussion of formation of impurities have been submitted in response to the Guidance Document for the Uniroyal 99% T (EPA Reg. No. 400-401), the Gustafson 80% FI (EPA Reg. No. 7501-45), or the Prochimie International 97% T (EPA Reg. No. 8236-8). Guidance Document requirements are still outstanding for these products.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Guidance Document dated 1/87 requires generic and product-specific data regarding preliminary analysis for all MPs.

Amvac Chemical Corporation (1988; MRID 40668602) submitted preliminary analysis data in response to the Guidance Document for the 95% T (EPA Reg. No. 5481-197). These data, presented in Confidential Appendix D, do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 62-1) regarding preliminary analysis of the 95% T (EPA Reg. No. 5481-197) because samples were not analyzed for impurities with certified limits ≥0.1%; furthermore, complete and detailed descriptions of the methods used for sample analysis were not submitted, nor were statements of precision and accuracy. Additional data are required.

In support of the amended registration to increase concentration and in response to Guidance Document requirements, Quimica Organica de Mexico (1988; MRIDs 40609601 and 40609602) submitted preliminary analysis data for the 96% T (EPA Reg. No. 10820-1). These data were reviewed by N. Gray (DEB No. 3880 dated 8/19/88) and found to satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 62-1) regarding preliminary analysis of the 96% T (EPA Reg. No. 10820-1). No additional data are required.

Uniroyal Chemical Company (1987; MRID 40506101) submitted preliminary analysis data in response to the Guidance Document for the 90% FI (EPA Reg No. 400-414); these data are presented in Confidential Appendix D. These data satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 62-1) regarding preliminary analysis of the 90% FI (EPA Reg No. 400-414). No additional data are required.

No preliminary analysis data have been submitted in response to the Guidance Document for the Uniroyal 99% T (EPA Reg. No. 400-401), the Gustafson 80% FI (EPA Reg. No. 7501-45), or the Prochimie International 97% T (EPA Reg. No. 8236-8). Guidance Document requirements for these products remain outstanding.

62-2. Certification of Limits

The Guidance Document dated 1/87 requires generic and product-specific data regarding certification of ingredient limits for all registered MPs.

Amvac Chemical Corporation (1988; MRID 40668602) submitted certification of ingredient limits in response to the Guidance Document for the 95% T (EPA Reg. No. 5481-197). These data, presented in Confidential Appendix A, satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the 95% T (EPA Reg. No. 5481-197). No additional data are required.

In support of the amended registration to increase concentration and Guidance Document requirements, Quimica Organica de Mexico (1988; MRIDs 40609601 and 40609602) submitted certification of limits for the 99% T (EPA Reg. No. 10820-1). These data have been reviewed by N. Gray (DEB No. 3880 dated 8/19/88) and found to satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the 96% T (EPA Reg. No. 10820-1). No additional data are required.

Uniroyal Chemical Company (1987; MRID 40506101) submitted certification of limits for the 90% FI (EPA Reg No. 400-414). These data, presented in Confidential Appendix A, do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the 90% FI (EPA Reg No. 400-414) because an explanation as to how the certified limits were established was not submitted. Additional data are required.

Uniroyal submitted a CSF dated 4/19/88 listing certified limits for the 99% T (EPA Reg. No. 400-401). These data are presented in Confidential Appendix A and satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the 99% FI (EPA Reg No. 400-401).

No certification of limits has been submitted in response to the Guidance Document for the Gustafson 80% FI (EPA Reg. No. 7501-45) and Prochimie International 97% T (EPA Reg. No. 8236-8). Guidance Document requirements are still outstanding for these products.

62-3. Enforcement Analytical Methods

The Guidance Document dated 1/87 requires generic and product-specific data requirements for PCNB regarding analytical methods to verify certified limits.

In response to the Guidance Document, Amvac Chemical Corporation (1988; MRID 40668602) submitted analytical enforcement methods for the determination of PCNB per se and impurities in the PCNB technical and formulated products. The method for the determination of impurities is discussed in Confidential Appendix E. [redacted] The analytical method for determination of PCNB discussed above and the method for determination of impurities discussed in Confidential Appendix E do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods to verify certified limits for the Amvac 95% T (EPA Reg. No. 5481-197) because methods for determination of certain impurities with certified limits at ≥0.1% were not submitted. Furthermore, for the submitted methods, the registrant failed to report or submit recovery data at different concentration levels to determine the accuracy of the method, and chromatograms of standards and samples. Additional data are required.

In support of the amended registration to increase concentration and Guidance Document requirements, Quimica Organica de Mexico (1988; MRID 40609602) submitted enforcement analytical methods for the 96% T (EPA Reg. No. 10820-1). These methods have been reviewed by N. Gray (DEB No. 3880 dated 8/19/88) and found to satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods to verify certified limits in the 96% T (EPA Reg. No. 10820-1). No additional data are required.

In response to the Guidance Document, Uniroyal Chemical Company (1989; MRID 40506101) submitted [redacted]

8/19/88). This method does not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the Uniroyal 90% FI (EPA Reg. No. 400-414), because validation data (precision and accuracy data) and a confirmatory analytical procedure were not submitted. Additional data are required.

No analytical methods to verify certified limits have been submitted in response to the Guidance Document for the Gustafson 80% FI (EPA Reg. No. 7501-45) and Prochimie International 97% T (EPA Reg. No. 8236-8). Guidance Document requirements for these products remain outstanding.

63-1 PHYSICAL AND CHEMICAL CHARACTERISTICS

The Guidance Document dated 1/87 requires generic data requirements but not product specific data requirements for all physical and chemical characteristics pertinent to the technical grade of the active ingredient.

Amvac (12/30/87; MRID 40668602) submitted physical and chemical characteristics in response to the Guidance Document for the 95% T (EPA Reg. No. 5481-197); these data are listed below in Table 2. These data do not satisfy the requirements of 40 CFR §158.190 (Guideline Reference No. 63-2 through 20) because the registrant did not include the testing methods and the substrate (PAI vs. TGAI) used. Data submitted for melting point, solubility, and vapor pressure are literature values which have not been properly validated. The stability data did not include data concerning the TGAI stability in the presence of metals and metal ions, at elevated temperatures ,and in sunlight. We note that the registrant has not submitted data concerning Guidelines 63-14 through -20. Additional data are required.

Quimica Organica de Mexico (1988; MRID 40609603) submitted physical and chemical characteristics in response to the Guidance Document and in support of the amended registration to increase concentration for the 96% T (EPA Reg. No. 10820-1). These data have been reviewed by N. Gray (DEB No. 3880 dated 8/19/88) and found to satisfy the required data for color, physical, state, odor, melting point, density, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, and stability. We note that the registrant has not submitted data concerning Guidelines 63-14 through -20.

No product chemistry data have been submitted for the Uniroyal 99% T (EPA Reg. No. 400-401), Uniroyal 90% FI (EPA Reg. No. 400-414), Gustafson 80% FI (EPA Reg. No. 7501-45), or Prochimie International 97% T (EPA Reg. No. 8236-8); thus a full complement of data on physical and chemical characteristics for these products are required.

Table 2. Physical and chemical properties of the Amvac 95% T (EPA Reg. No. 5481-197); data are from MRID 40668602.

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method]
63-2.	Color	**off white to cream**
63-3.	Physical state	**crystalline solid**
63-4.	Odor	**slight musty odor**
63-5.	Melting point	**141-146 C[a]**
63-6.	Boiling point	**328 C with decomposition[a]**
63-7.	Density, bulk density, or specific gravity	**0.5-0.9 g/cc, 1.72 g/cc true density**
63-8.	Solubility	Solvent / Solubility / Temperature water 0.44 mg/L 20 C ethanol 2.0 g/100 mL 25 C toluene 50.0% w/w 25 C dichloroethane 20.0% w/w 25 C Soluble in CS_2, benzene, chloroform, ketones, aromatic and chlorinated hydrocarbons.[a]
63-9.	Vapor pressure	**5.0×10^{-5} mm Hg at 20 C[a]**
63-10.	Dissociation constant	**does not dissociate, pH is due to impurities**
63-11.	Octanol/water partition coefficient	**p = 697, $K_{o/w}$ = 2.84**
63-12.	pH	**2.5-6**
63-13.	Stability	**stable >3 years as a solid**

[a] Data obtained from the following reference: 1984; Quitozene, Environmental Health Criteria 41, World Health Organization, Geneva.

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Product Chemistry References (used):

40066901 Boehme, C. (1986) Product Chemistry, Series 61: Terrazan PCNB Technical 96%: Supplement to Product Chemistry Submitted April 17, 1986: QOMSA 1986-1. Unpublished compilation prepared by Quimica Organica de Mexico, S.A. de C.V. 14 p.

40066902 Boehme, C. (1986) Product Chemistry, Series 62: Terrazan PCNB Technical 96%: Supplement to Product Chemistry Submitted April 17, 1986: QOMSA 1986-2. Unpublished compilation prepared by Quimica Organica de Mexico, S.A. de C.V. 65 p.

40287901 Drozdick, M. (1987) Product Specific Data for Terraclor 90% Dust Concentrate, Part 1. Unpublished compilation prepared by Uniroyal Chemical Co., Inc. 16 p.

40506101 Drozdick, M. (1988) Preliminary Analysis, Certification Statement and Analytical Method for Terraclor 90% Dust Concentrate: Laboratory Project ID: MDD071687 1 thru 5. Unpublished compilation prepared by Uniroyal Chemical Co., Inc. 10 p.

40609601 Carrilo, F.; Mertz, J. (1988) Terrazan PCNB Technical 99%: Product Chemistry Data--Product Identity and Composition. Unpublished compilation prepared by Quimica Organica de Mexico, S.A. de C.V. in cooperation with Uniroyal Chemical Co., Inc. 9 p.

40609602 Carrilo, F.; Blaszczynski, E. (1988) Terrazan PCNB Technical 99%: Product Chemistry Data--Analysis and Certification of Product Ingredients: Project No. 8825. Unpublished compilation prepared by Quimica Organica de Mexico, S.A. de C.V. in cooperation with Uniroyal Chemical Co., Inc. 22 p.

40609603 Carrilo, F.; Batorewicz, W.; Woolson, E. (1988) Terrazan PCNB Technical 99%: Product Chemistry Data--A Compilation of Physical and Chemical Characteristics: Project No. 8817. Unpublished study prepared by Quimica Organica de Mexico, S.A. de C.V., and Uniroyal Chemical Co., Inc. in cooperation with EPL Bio-Analytical Services, Inc. 17 p.

40668601 Feiler, W. (1988) PCNB: Product Identity and Composition. Unpublished compilation prepared by Amvac Chemical Corp. 42 p.

40668602 Feiler, W. (1988) PCNB: Analysis and Certification of Product Ingredients. Unpublished study prepared by Amvac Chemical Corp. 23 p.

Feiler, W. (1987) PCNB: Product Identity and Composition. Confidential Statement of Formula for the 95% T. (No MRID No. assigned).

Feiler, W. (1987) PCNB: Physical and Chemical Characteristics. Unpublished study prepared by Amvac Chemical Corp. (No MRID No. assigned). 3 p.

Product Chemistry Citations (not used):

[The following MRIDs are irrelevant or contained data pertaining only to end-use products.]

00152549 Ciba-Geigy Corporation (1985) Ridomil + PCNB Prepack [Product Chemistry Data]. Unpublished compilation. 36 p.

00152564 Baldi, A. (1985) Letter sent to G. Werdig dated Jul 29, 1985: PCNB EPA data call-in notice of May 8, 1985. Prepared by Aceto Agricultural Chemicals Corp. 3 p.

00153209 Quimica Organica de Mexico, S.A. (1985) Report on the Production of PCNB with Less than 0.1% HCB by Quimica Organica de Mexico, S.A.: Progress Report No. 4. Unpublished study. 6 p.

00155496 Rhone-Poulenc Inc. (1985) Mocap PCNB Product Chemistry. Unpublished compilation. 46 p.

00155555 Tucker, D., comp. (1986) Product Identity and Disclosure of Ingredients: [PCNB-M 10-3G]. Unpublished compilation prepared by Micro-Flo Co. 35 p.

00155556 Tucker, D., comp. (1986?) Preliminary Analysis of Product Samples: [Analysis and Certification of Product Ingredients] PCNB-M 10-3G:. Unpublished compilation prepared by Micro-Flo Co. 7 p.

00155557 Tucker, D., comp. (1986?) Physical and Chemical Characteristics: [PCNB-M 10-3G]. Unpublished compilation prepared by Micro-Flo Co. 25 p.

00158280 Quimica Organica de Mexico, S. A. de C. V. (19??) Beginning Materials [Including Other Product Chemistry Data of Terrazan PCNB Technical]. Unpublished study. 37 p.

00161255 Chevron Chemical Co. (1986) Product Identity & Composition: Orthocide PCBN 10-20 Dust: Laboratory Project Identification 8607892. Unpublished compilation. 12 p.

00161256 Chevron Chemical Co. (1986) Analysis & Certification of Product Ingredients: Orthocide PCNB 10-20 Dust: Laboratory Project Identification 8607893. Unpublished compilation. 13 p.

00161257 Chevron Chemical Co. (1986) Physical and Chemical Characteristics: Orthocide PCNB 10-20 Dust: Laboratory Project Identification 8607894. Unpublished compilation. 47 p.

00162372 Gustafson, Inc. (1986) Product Chemistry Data: Vivatax PCNB-Lindane Flowable Fungicide. Unpublished study. 21 p.

40062301 Mote, J.; Rosa, F.; Wurther, C. (1987) Product Chemistry Data: Gustafson TSX Apron Dust Seed Treatment: Laboratory Project ID: R105:74-1. Unpublished compilation prepared by Gustafson, Inc. 14 p.

40225101 Tucker, D. (1986) 12 Month Storage Stability Study for PCNB-M 10-3G: Laboratory Project ID: MICRO-FLO PCNB-M-EU-1. Unpublished study prepared by Chempax. 6 p.

40293301 Williams, D. (1987) Clean Crop PCNB Granules No. 10, Soil Fungicide: Product Chemistry Information: Study No. 87-14A. Unpublished compilation prepared by Platte Chemical Co., Inc. 4 p.

40334601 Boehme, C. (1987) Production of PCNB with Less than 0.1% HCB by Quimica Organica de Mexico, S.A. de C.V.: Progress Report No. 5: QOMSA-1987-1. Unpublished study prepared by Quimica Organica de Mexico, S.A. de C.V. 11 p.

40398001 Klettke, M. (1987) Cooke Fungicide: Product Chemistry Data. Unpublished study prepared by Cooke Laboratory Products. 28 p.

40414901 Carrillo, F. (1987) Pentachloronitrobenzene Technical: Product Identity and Disclosure of Ingredients: QOMSA-1987-2. Unpublished compilation prepared by Quimica Organica de Mexico. 4 p.

40414902 Carrillo, F.; Blaszczynski, E.; Drozdlck, M.; et al. (1987) Pentachloronitrobenzene Technical: Product Chemistry Data--A Compilation of Physical and Chemical Characteristics: QOMSA-1987-3. Unpublished compilation prepared by Quimica Organica de Mexico in cooperation with Uniroyal Chemical Co., and others. 50 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE PCNB TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Partially	40609601 40609602 40668601	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	40609601 40609602 40668601	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	TGAI	Partially	40609601 40609602 40668602	Yes[6]
Physical and Chemical Characteristics[7]				
63-2. Color	TGAI	Partially	40609603 40668602	Yes[8]
63-3. Physical State	TGAI	Partially	40609603 40668602	Yes[9]
63-4. Odor	TGAI	Partially	40609603 40668602	Yes[10]
63-5. Melting Point	TGAI	Partially	40609603 40668602	Yes[11]
63-6. Boiling Point	TGAI	Partially	40609603 40668602	Yes[12]
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Partially	40609603 40668602	Yes[13]
63-8. Solubility	TGAI or PAI	Partially	40609603 40668602	Yes[14]
63-9. Vapor Pressure	TGAI or PAI	Partially	40609603 40668602	Yes[15]
63-10. Dissociation Constant	TGAI or PAI	Partially	40609603 40668602	Yes[16]
63-11. Octanol/Water Partitioning Coefficient	PAI	Partially	40609603 40668602	Yes[17]
63-12. pH	TGAI	Partially	40609603 40668602	Yes[18]
63-13. Stability	TGAI	Partially	40609603 40668602	Yes[19]

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

1. Additional data requirements are listed in the following Table B, "Generic Data Requirements for PCNB Manufacturing-Use Products".

2. Test substance: PAI = purified active ingredient; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

3. These references were submitted in response to the PCNB Guidance Document dated 1/87. Underlining indicates references containing data reviewed in this update.

4. Information concerning: (i) the relative percentages of the beginning materials, a description of the conditions (e.g., temperature, pressure, pH, humidity) controlled during each step of the process, and quality control procedures employed during production are required for the Amvac 95% T (EPA Reg. No. 5481-197); (ii) The source of the technocal for the Uniroyal 90% FI (EPA Reg. No. 400-414); and (iii) an explanation of what changes, if any, have been made in the manufacturing process used to produce the crude PCNB for the Quimica 96% T (EPA Reg. No. 10820-1). Complete infromation concerning starting materials and the manufacturing processes are required for the Uniroyal Chemical Co. 99% T (EPA Reg. No. 400-401) and Prochimie International 97% T (EPA Reg. No. 8236-8); in their submissions, the registrants must explain changes, if any, that have been made in the manufacturing process(es) to reduce the levels of HCB to <0.1% by weight of the TGAI.

5. No data are required for the Amvac 95% T (EPA Reg. 5481-197), the Quimica 96% T (EPA Reg. No. 10820-1), or the Uniroyal 90% FI (EPA Reg. No. 400-414) concerning the formation of impurities. Complete infromation concerning the formation of impurities are required for the Uniroyal Chemical Co. 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8236-8).

TABLE A. (Continued).

6. Analysis of all impurities for which certified limits of ≥0.1% have been established is required along with a complete description of the analytical methods used for analysis of the TGAI and impurities and validation data (precision and accuracy) for methods used in the prelimianry analysis of the Amvac 95% T (EPA Reg. No. 5481-197).

7. As required by 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, and stability). There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing-use products.

8. Data on color are required for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8). For the Amvac 95% T (EPA.Reg. No. 5481-197), the substance analyzed (PAI or TGAI) must be reported.

9. Data on physical state are requried for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8). For the Amvac Corp. 95% T (EPA Reg. No. 5481-197) the substance analyzed (PAI or TGAI) must be reported.

10. Data on odor are required for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8). For the Amvac Corp. 95% T (EPA Reg. No. 5481-197) the substance analyzed (PAI or TGAI) must be reported.

11. Data on melting point are requried for the Uniroyal 99% T (EPA Reg. No. 400-401) and (iii) the Prochimie International 97% T (EPA Reg. No. 8326-8). For the Amvac Corp. 95% T (EPA Reg. No. 5481-197) the substance analyzed (PAI or TGAI) and the method used must be reported, along with validated data on melting point.

12. The substance analyzed (PAI or TGAI) must be reported for the Amvac, Inc. 95% T, along with complete information concerning boiling point for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8).

TABLE A. (Continued).

13. The method used and substance analyzed (PAI or TGAI) must be submitted for the Amvac, Inc. 95% T, along with complete information concerning density, bulk density, or specific gravity for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8).

14. Validated data concerning solubility, the method used and substance analyzed (PAI or TGAI) must be submitted for the Amvac, Inc. 95% T, along with complete information concerning solubility for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8).

15. Complete data on vapor pressure are required for the following MPs: The method used and substance analyzed (PAI or TGAI) must be submitted for the Amvac, Inc. 95% T, along with complete information concerning vapor pressure for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8).

16. For the Amvac Corp. 95% T (EPA Reg. No. 5481-197) the substance analyzed (PAI or TGAI) and the method used must be reported. Complete data on dissociation constant are required for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8).

17. The method used and substance analyzed (PAI or TGAI) must be submitted for the Amvac, Inc. 95% T, along with complete information concerning octanol/water partition coefficient for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8).

18. The method used and substance analyzed (PAI or TGAI) must be submitted for the Amvac, Inc. 95% T, along with complete information concerning pH for the Uniroyal 99% T (EPA Reg. No. 400-401)and the Prochimie International 97% T (EPA Reg. No. 8326-8).

19. The method used and substance analyzed (PAI or TGAI) must be submitted for the existing data on the Amvac, Inc. 95% T, along with data on the stability in the presence of metal ions, elevated temperature, and sunlight. Complete information concerning stability are required for the Uniroyal 99% T (EPA Reg. No. 400-401) and the Prochimie International 97% T (EPA Reg. No. 8326-8).

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR PCNB MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Composition	MP	Partially	40287901 40506101 40609601 40609602 40668601 40668902	Yes[4]
61-2. Beginning Materials & Production/Formulation Process	MP	Partially	40287901 40609601 40609602 40668601	Yes[5]
61-3. Formation of Impurities	MP	Partially	40287901 40609601 40609602 40668601	Yes[6]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	MP	Partially	40506101 40606901 40606902 40668602	Yes[7]
62-2. Certified Limits	MP	Partially	40506101 40606901 40606902 40668602	Yes[8]
62-3. Enforcement Analytical Methods	MP	Partially	40506101 40609602 40668602	Yes[9]
Physical and Chemical Characteristics[10]				
63-2. Color	MP	Partially	40609603 40668602	Yes[11]
63-3. Physical State	MP	Partially	40609603 40668602	Yes[12]
63-4. Odor	MP	Partially	40609603 40668602	Yes[13]
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	40609603 40668602	Yes[14]
63-12. pH	MP	Partially	40609603 40668602	Yes[15]

(Continued, footnotes follow)

TABLE B. (Continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
62-14. Oxidizing or Reducing Action	MP	No		Yes[16]	
62-15. Flammability	MP	No		Yes[17]	
63-16. Explodability	MP	No		Yes[18]	
63-17. Storage Stability	MP	No		Yes[19]	
63-18. Viscosity	MP	No	N/A	No[20]	
63-19. Miscibility	MP	No	N/A	No[21]	
63-20. Corrosion Characteristics	MP	No		Yes[22]	
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

1. Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the PCNB Technical Grade of the Active Ingredient".

2. Test substance: PAI = purified active ingredient; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

3. These references were submitted in response to the PCNB Guidance Document dated 1/87. Underlining indicates references containing data reviewed in this update.

4. No additional data are required for the Quimica 96% T (EPA Reg. No. 44215-129), the Uniroyal 99% T (EPA Reg. No. 400-401), or the Amvac Corp. 95% T (EPA Reg. No. 5481-197). Data regarding the nominal concentration CAS Reg. No., and EPA Reg. No. of the source product (TGAI) are required for the Uniroyal 90% FI along with the nominal concentration and purpose of the inert ingredient. Complete data concerning product identity and disclosure of ingredients are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Prochimie International 97% T (EPA Reg. No. 8326-8), and the Gustafson, Inc. 80% FI (EPA REG. No. 7501-45); the submissions must indicate that HCB is present at <0.1% by weight of the TGAI.

TABLE B. (Continued).

5. Information concerning: (i) the relative percentages of the beginning materials, a description of the conditions (e.g., temperature, pressure, pH, humidity) controlled during each step of the process, and quality control procedures employed during production are required for the Amvac 95% T (EPA Reg. No. 5481-197); (ii) The source of the technocal for the Uniroyal 90% FI (EPA Reg. No. 400-414); and (iii) an explanation of what changes, if any, have been made in the manufacturing process used to produce the crude PCNB for the Quimica 96% T (EPA Reg. No. 10820-1). Complete infromation concerning starting materials and the manufacturing processes are required for the following MPs: (i) Uniroyal Chemical Co. 99% T (EPA Reg. No. 400-401), (ii) Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45), and (iii) Prochimie International 97% T (EPA Reg. No. 8236-8); in their submissions, the registrants must explain changes, if any, that have been made in the manufacturing process(es) to reduce the levels of HCB to <0.1% by weight of the TGAI..

6. No data are required for the Amvac 95% T (EPA Reg. 5481-197), the Quimica 96% T (EPA Reg. No. 10820-1), or the Uniroyal 90% FI (EPA Reg. No. 400-414) concerning the formation of impurities. Complete infromation concerning the formation of impurities are required for the Uniroyal Chemical Co. 99% T (EPA Reg. No. 400-401), the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45), and the Prochimie International 97% T (EPA Reg. No. 8236-8).

7. Analysis of all impurities for which certified limits of ≥0.1% have been established is required along with a complete description of the analytical methods used for analysis of the TGAI and impurities and validation data (precision and accuracy) for methods used in the prelimianry analysis of the Amvac 95% T (EPA Reg. No. 5481-197).

8. An explaination as to how the certified limits were determined is required for Uniroyal 99% T (EPA Reg. No. 400-401) and 90% FI (EPA Reg. No. 400-414). Complete data regarding certified limits are required for the Prochimie International 97% T (EPA Reg. No. 8326-8) and the Gustafson, Inc. 80% FI (EPA REG. No. 7501-45).

9. Amvac Corp. must submit data on accuracy for the methods submitted for the 95% T (EPA Reg. No. 5481-197), and also additional validated methods for determining all impurities for which certified limits of ≥0.1% have been established. The methods submitted by Uniroyal must be validated for the 99% T (EPA Reg. No. 400-401) and 90% FI (EPA Reg. No. 400-401), and a confirmatory procedure must be submitted. Complete information on enforcement analytical methodology are required for the Prochimie International 97% T (EPA Reg. No. 8326-8), and the Gustafson, Inc. 80% FI (EPA REG. No. 7501-45).

TABLE B. (Continued).

10. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use products which contain only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the PCNB Technical Grade of the Active Ingredient."

11. Data on color are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45) For the Amvac 95% T (EPA.Reg. No. 5481-197), the substance analyzed (PAI or TGAI) must be reported.

12. Data on physical state are requried for the Uniroyal 99% T (EPA Reg. No. 400-401), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45). For the Amvac Corp. 95% T (EPA Reg. No. 5481-197) the substance analyzed (PAI or TGAI) must be reported.

13. Data on odor are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45). For the Amvac Corp. 95% T (EPA Reg. No. 5481-197) the substance analyzed (PAI or TGAI) must be reported.

14. The method used and substance analyzed (PAI or TGAI) must be submitted for the Amvac, Inc. 95% T, along with complete information concerning density, bulk density, or specific gravity for the Uniroyal 99% T (EPA Reg. No. 400-401), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45).

15. Complete data on pH are required for the following MPs: (i) Aceto Chemical Co. 98% T (EPA Reg. No. 2749-181); (ii) Mobay Corp. 98% T (EPA Reg. No. 11556-30); and (iii) Mobay 82% FI (EPA Reg. No. 11556-55).

16. Data on oxidizing/reducing action are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Amvac 95% T (EPA.Reg. No. 5481-197), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45).

TABLE B. (Continued).

17. Data on flammibility are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Amvac 95% T (EPA.Reg. No. 5481-197), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45).

18. Data on explodability are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Amvac 95% T (EPA.Reg. No. 5481-197), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45).

19. Data on storage stability are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Amvac 95% T (EPA.Reg. No. 5481-197), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45).

20. Data on viscosity are not required since the products are solid.

21. Data on miscibility are not required since the product is not an emulsifiable liquid and to be diluted with petroleum solvents.

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22. Data on corrosion characteristics are required for the Uniroyal 99% T (EPA Reg. No. 400-401), the Amvac 95% T (EPA.Reg. No. 5481-197), the Prochimie International 97% T (EPA Reg. No. 8326-8), the Uniroyal 90% FI (EPA Reg. No. 400-414), and the Gustafson, Inc. 80% FI (EPA Reg. No. 7501-45).

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CONFIDENTIAL

PENTACHLORONITROBENZENE (PCNB)

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 3 Page(s)
Appendix B: 2 Page(s)
Appendix C: 2 Page(s)
Appendix D: 1 Page(s)
Appendix E: 1 Page(s)

Confidential Appendices to the Scientific Review of the Follow-up Report for the pesticide pentachloronitrobenzene by the Dietary Exposure Branch [Confidential FIFRA Trade Secret/CBI].

PCNB Product and Residue Chemistry Update

Page _____ is not included in this copy.

Pages 26 through 34 are not included in this copy.

The material not included contains the following type of information:

__X__ Identity of product inert ingredients

__X__ Identity of product impurities

__X__ Description of the product manufacturing process

__X__ Description of product 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.

DYNAMAC
CORPORATION

Final Report

PCNB
Task 4. Residue Chemistry. Registration Standard Update

APRIL 25, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

PCNB

REGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 4

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PCNB

REGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 4

INTRODUCTION

The updated Index to Pesticide Chemicals dated 3/89 lists registered uses on beans (dry, green, kidney, lima, and snap), broccoli, Brussels sprouts, cabbage, cauliflower, cotton, garlic, peppers, and tomatoes. PCNB is registered for seed treatments on barley, beans, corn, cottonseed, garlic seed cloves, oats, peanuts, peas, potato seed pieces, rice, safflower, sorghum, soybeans, sugar beets, and wheat. PCNB formulations registered for food and feed uses are the 10, 20, 25, 30, and 40% dust (D), the 6.5, 10, and 30% granular (G), the 14, 30, 35, and 75% wettable powder (WP), 23.2, 23.4, 23.8, 23.9, and 24% emulsifiable concentrate (EC), 17% flowable concentrate (FlC), and 10, 17.68, 20, 22.6, 23.1, 23.2, 23.7, 24, and 25% ready-to-use (RTU) formulations.

The PCNB Guidance Document dated 1/87 identifies outstanding data requirements for plant and animal metabolism, analytical methods, storage stability data, residue data on potatoes, garlic, broccoli, Brussels sprouts, cabbage, cauliflower, beans, peppers, tomatoes, bananas including plantains, cottonseed, and peanuts, and data concerning seed treatments. It was determined that a tolerance proposal and supporting residue data are needed for soybean commodities grown from treated seed.

The PCNB Guidance Document dated 1/87 concluded that the available data are insufficient to assess the maximum expected residues of PCNB in or on lettuce, strawberries, alfalfa, and clover resulting from use under intrastate registrations and required tolerance proposals and supporting residue data, or, alternatively, cancellations of the registrations.

In response to the Guidance Document, data have been submitted pertaining to storage stability (MRIDs 40921600 and 40921601), potatoes (MRID 40816701), processed potatoes (MRIDs 40070401, 40088401, and 40457401), broccoli (MRID 40816702), cabbage (MRID 40816703), beans (MRID 40816704), peppers (MRID 40816705), peanuts (MRID 41002507), and seed treatment (MRID 40862901), which have been reviewed or are currently under review by the Agency. Data concerning plant metabolism (MRIDs 41341201, 41341202, and 41341203), animal metabolism (MRIDs 41303301, 41341205, 41303101 and 41341204), and cottonseed (MRID 41341206) are reviewed in this update for their adequacy in fulfilling the outstanding data requirements.

A tolerance of 0.1 ppm has been established for residues of PCNB per se in or on cottonseed (40 CFR 180.291[a]), and tolerances with regional registration of 0.2 ppm have been established for the combined residues of PCNB and its metabolites pentachloroanaline (PCA) and methyl pentachlorophenyl sulfide (MPCPS) in or on collards, kale, and mustard greens (40 CFR 180.291[b]). Interim tolerances of 0.1 ppm are in effect for residues of PCNB in or on bananas, beans, broccoli, Brussels sprouts, cabbage cauliflower, garlic, peppers, potatoes and tomatoes; an interim tolerance of 1 ppm is in effect for peanuts (40 CFR 180.319). Tolerances limiting the amount of the impurity hexachlorobenzene (HCB) have been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on numerous plant and animal commodities (PP#1F1083, Amendment of 1/83).

SUMMARY

The following residue chemistry data are outstanding:

- Data on plant and animal metabolism, residue analytical methods, and storage stability.
- Tolerances must be proposed and supporting residue data submitted for alfalfa, clover, and lettuce for which uses are permitted under intrastate registrations, and corn, soybeans, peas, sugar beets, and wheat for which seed treatments are registered, and bean vines and hay.
- Residue data on potatoes, broccoli, cabbage, cauliflower, Brussels sprouts, beans, peppers, tomatoes, bananas, cottonseed, peanuts, and peanut hulls.
- Processing studies on potatoes, cottonseed, peanuts, corn, and soybeans.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The qualitative nature of the residue in plants is not adequately understood. The PCNB Guidance Document (1/87) requires data depicting the metabolism of PCNB in peanuts, cabbage, and potatoes. Uniroyal Chemical Co., in its 90-day response to the Guidance Document, requested a time extension for submitting the required plant metabolism data and indicated their intention to submit the data in 7/88; DEB had no objection to the registrant's proposal (DEB No. 2781; 11/16/87). In a second request for a time extension, the registrant stated that the data would be submitted on 12/31/89; DEB recommended in favor of the request

(K. Dockter, DEB No. 4857; 2/21/89). Uniroyal has submitted progress reports for metabolism studies on potatoes, peanuts, and cabbage (1989; MRIDs 41341201, -02, and -03) and has stated their intention to complete the studies in 3/90. According to these reports, data from combustion/radioassay of [^{14}C]PCNB-treated plants indicate that total radioactive residues were 2.6 ppm in or on potato tubers, 7.5 ppm in or on potato vines, 1520.8 ppm in peanut roots, 42.3 ppm in or on peanut vines, 128.3 ppm in or on peanut shells, and 5.16 ppm in or on peanut nutmeats; data on total radioactivity in or on cabbage were not provided.

Data depicting the uptake and translocation of [^{14}C]PCNB following registered seed treatments were submitted and are addressed in this review in the section "Crops with Seed Treatments Only." The following additional data are required:

- Data depicting the uptake, distribution, and metabolism of ring-labeled [^{14}C]PCNB in three dissimilar crops (peanuts, potatoes, and cabbage). A completely characterized test substance representative of technical PCNB used in commercial formulations (including impurities) must be applied under conditions representing normal cropping practices and at rates high enough to permit characterization of ^{14}C-residues. The identities and quantities of residues in mature plant parts must be determined in order to elucidate terminal residues. Confirmation of the identities of residues using a suitable method such as mass spectrometry (MS) or high-performance liquid chromatography (HPLC) is also required. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to ascertain that the methods are capable of adequately recovering and quantifying all metabolites of concern.

References (used):

MRIDs: 41341201. 41341202. 41341203.

Discussion of the data:

N/A.

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The qualitative nature of the residue in animals is not adequately understood. The PCNB Guidance Document (1/87) requires data depicting the metabolism of PCNB in ruminants and

poultry. Uniroyal Chemical Co., in its 90-day response to the Guidance Document, requested a time extension for submitting the required animal metabolism data and indicated their intention to submit the data in 7/88; DEB had no objection to the registrant's proposal (DEB No. 2781; 11/16/87). In a second request for a time extension, the registrant stated that the data would be submitted on 12/31/89; DEB recommended in favor of the request (K. Dockter; DEB No. 4857; 2/21/89). Uniroyal has submitted two volumes of data (1989; MRIDs 41303301 and 41341205) pertaining to the metabolism of PCNB in lactating goats. These data do not fulfill the requirement for metabolism data on ruminants because discrepancies exist between the descriptions of the in-life portion of the study and tissue-combustion data (MRID 41303301) and data in the submission containing metabolite characterization data (MRID 41341205). Furthermore, the registrant did not provide adequate data to support the quantifications of metabolites reported. The registrant submitted data on poultry metabolism (1988, 41303101; 1989, 41341204) which were incomplete; the registrant stated their intent to complete the study in 3/90.

The following additional data are required:

- Data depicting the metabolism of ring-labeled [^{14}C]PCNB in ruminants and poultry. For the poultry study in progress (MRID 41341204), the dietary feeding level, and conditions under which tissue hydrolysis were conducted must be reported. The distribution and identities of residues must be determined in eggs, muscle, liver, fat, and skin. For the submitted study on goats, the registrant must explain the discrepancies in the two submissions and present evidence that the data in MRID 41341205 reflect analysis of tissues from the same animal described in MRID 41303301. In addition, the registrant must report the fraction of the TRR partitioned into each solvent used in the extraction and into bound residue for milk, fat, and liver (and muscle, if warranted by the TRR in muscle), and for each extract that was analyzed by HPLC, the registrant must provide the amount of radioactivity applied in each HPLC analysis and the amount of radioactivity detected in the identified radioactive zones. Data depicting the nature of the residues in swine may also be required if studies with ruminants reveal that the metabolism of PCNB in these animals differs from that in rats. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to ascertain that the methods are capable of adequately recovering and quantifying all metabolites of concern.

References (used):

MRIDs: 41303301. 41341205. 41341204. 41303101.

Discussion of the data:

Goats. Amvac Chemical Corporation (1989; MRID 41303301) submitted data pertaining to the metabolism of PCNB in ruminants. Two lactating goats were dosed orally with uniformly ring-labeled [^{14}C]PCNB (radiochemical purity: 96.6%) administered in capsules for 5 consecutive days. One goat was dosed at a level of 1.36 g/goat/day (25 mg/kg of body weight, equivalent to 714 ppm in the diet, specific activity of 1,556 dpm/μg) and the other goat was dosed at a level of 2.08 g/goat/day (50 mg/kg of body weight, equivalent to 947 ppm in the diet, specific activity of 1,012 dpm/μg). A third goat served as a control and was administered empty capsules. Milk, urine and feces samples were collected twice daily and were stored frozen pending analysis. The goats were sacrificed 6 hours after the last dose, and samples of blood, muscle, liver, kidneys, fat (renal and omental), bile, urine, and gastrointestinal (GI) tract were collected. Blood was refrigerated until analysis was complete, all other samples were stored frozen pending analysis.

Total Radioactive Residues (TRR)

Tissue samples, feces, and blood were combusted and analyzed for TRR by liquid scintillation spectrometry (LSS); samples of bile, milk, urine, GI tract contents, and wash and pan rinses were analyzed directly by LSS. Recovery of the total dose and distribution of total radioactive residue are given below in Tables 1 and 2.

Table 1. Percent recovery of total dose in matrices of lactating goats administered [^{14}C]PCNB.

Matrix	Percent recovery at dietary level of 714 ppm	947 ppm
Liver	0.18	0.12
Kidney	0.02	0.02
Muscle	<0.01	<0.01
Fat (omental)	0.13	0.02
Fat (renal)	0.12	<0.01
Milk	0.34	0.21
Blood	<0.01	<0.01
Bile	0.03	0.02
GI tract + contents	16.60	15.16
Urine (cumulative)	30.51	20.00
Urine (bladder)	0.13	ND
Feces (cumulative)	35.90	41.02
Pan rinse	0.20	0.44
Total	84.16	77.01

Table 2. Total radioactive residues (TRR) in milk and tissues of lactating goats administered [^{14}C]PCNB.

Matrix	TRR (ppm as PCNB equivalents) at 714 ppm	947 ppm
Liver	13.371	13.353
Kidney	10.295	11.204
Muscle	0.541	0.483
Fat (omental)	15.162	12.792
Fat (renal)	15.615	9.430
Milk	2.866[a]	1.759[b]

[a] Average obtained by the reviewer from reported TRR values of 0.347-5.981 ppm for days 1-5 of treatment.

[b] Average obtained by the reviewer from reported values of 0.223-3.553 ppm for days 1-5 of treatment.

Extraction

Data on the extraction and characterization of PCNB metabolites in goats have been submitted by Uniroyal Chemical Company (1989, MRID 41341205). The Uniroyal data are reviewed below under the assumption that the metabolite characterization performed by

Uniroyal was done in matrices from the goat dosed at a dietary level of 947 ppm and described above.

It is noted, however, that although the Uniroyal study was performed with goats dosed orally with [^{14}C]PCNB (at 50 mg/kg of body weight) for 5 consecutive days (as reported by Amvac), there is no assurance that both the Uniroyal study (MRID 41341205) and the above Amvac study (MRID 41303301) refer to the same animals. In particular, (i) there is no explicit statement indicating that both studies refer to the same animal; (ii) the only TRR value reported in the Uniroyal study, that for kidney, is 49.1 ppm, whereas the TRR for kidney reported in the Amvac study is 11.2 ppm; (iii) the Uniroyal study reported that liver, kidney, and fat were the only tissues that showed radioactive levels above background, whereas the Amvac study (Table 2) reported a muscle TRR of 0.483 ppm; and (iv) the specific activity of the [^{14}C]PCNB used in the Uniroyal study was reported as 1,040 dpm/μg, whereas that used in the Amvac study was 1,012 dpm/μg.

Urine samples were passed through a Baker solid phase extraction (SPE) C-18 cartridge, washed with water, eluted from the cartridge with methanol and then analyzed by HPLC.

Milk samples were extracted twice with ethyl acetate. The ethyl acetate extracts were concentrated and partitioned with hexane and acetonitrile (ACN). The hexane and ACN fractions were concentrated to near dryness, and the residues from each fraction were dissolved in methanol and analyzed by HPLC. No other details were given.

Subsamples of liver and kidney were extracted according to the Bligh-Dyer method; however, no details were given other than the indication that methanol:chloroform (2:1, v/v) was used in the extraction. The extracts were passed through C-18 SPE cartridges, washed with water, eluted from the cartridge with methanol, and then analyzed by HPLC. Suspended liver and tissue samples were subjected to proteolysis (P5147 protease) for 18 hours at 37 C to release bound residues. The solubilized material was passed through a C-18 SPE cartridge, washed with water, eluted from the cartridge with methanol, and then analyzed by HPLC.

Fat subsamples were extracted with chloroform. The chloroform was evaporated and the samples were partitioned with hexane and ACN. The ACN fraction was concentrated and analyzed by HPLC. No other details were given.

The distribution of total radioactivity in extracts of liver and kidney is summarized in Table 3. Only 44% of the TRR in liver was extractable into organic solvents. The fate of the remaining 56% of the liver TRR was unaccounted for; an unspecified amount of the unextractable residue became solubilized by protease

treatment. Up to 74% of the TRR of kidney was extractable into organic solvents, the remaining 26% was bound residue. Protease treatment of the bound residue in kidney released up to an additional 19% of the TRR.

Little or no data were available concerning the distribution of radioactivity in extracts of milk and fat. In milk, it was reported that 87% of the radioactivity was extractable into organic solvents, the remaining 13% was unaccounted for. It was not explained how the radioactivity partitioned into the various organic solvents or what fraction of the radioactivity was lost or remained as bound residue.

In fat, it was reported that 84% of the radioactivity partitioned into ACN; the remaining 16% was unaccounted for. The type of fat, omental or renal, was not specified. In addition, it was not explained how the radioactivity partitioned into the various organic solvents or what fraction of the radioactivity was lost or remained as bound residue.

Table 3. Distribution of total radioactivity in extracts of liver and kidney from a lactating goat administered [^{14}C]PCNB orally.

Fraction	Percent of total radioactivity in Liver	Kidney
Non-bound		
chloroform	24	46
methanol/water	20	28
Total non-bound	44	74
Bound		
Released by protease	-[a]	19
Not released by protease	-[b]	7[c]
Total bound	56	26
Total	100	101

[a] Unspecified. The author indicated only that the residue bound to the pellet after extraction became water soluble after protease treatment.

[b] Unspecified.

[c] Calculated by the reviewer, by subtracting reported value for protease-released material from reported total bound.

Characterization of Residues

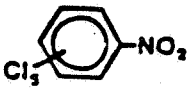
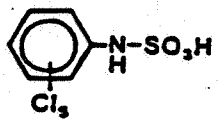
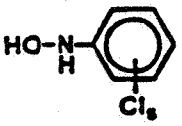
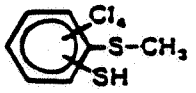
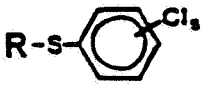
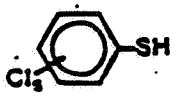
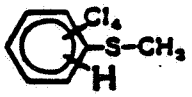
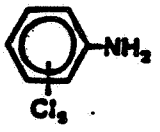
Soluble residues in urine and in extracts of liver, kidney, milk, omental fat, and renal fat were analyzed by high performance liquid chromatography (HPLC). Polar metabolites in liver and kidney were hydrolyzed with 1 M anhydrous methanol/hydrochloric acid at 60 C for 10 minutes prior to analysis by HPLC. A urinary metabolite thought to be metabolite II was hydrolyzed by heating at 80 C in 0.1 N sodium hydroxide for 2 hours. HPLC analysis was conducted using a 20-100% solution of methanol. Metabolite structures were verified by mass spectral analysis. The molecular structures of PCNB and metabolites identified in this study are depicted in Table 4.

The reported results of residue analysis in goat matrices are summarized in Table 5. It is noted that, although [^{14}C]radioactivity was monitored during analysis and sample radiochromatograms were included in the submission, no experimental data (such as area percent under the radioactivity trace or recoveries of radioactivity after HPLC) were available for review. This omission, coupled with the incomplete data on solvent partition, made it impossible to verify the values for distribution of PCNB metabolites reported in Table 5 and to estimate independently the fractions of TRR lost or unaccounted for.

In particular, as shown in Table 5, the registrant reported that 100% of the TRR in fat was accounted for as metabolite VIII, yet only 84% was accounted for as having been partitioned into ACN and the remaining 16% was unaccounted for. Likewise, the registrant reported that 96% of the TRR in milk was metabolite VIII, yet only 87% of the radioactivity was reported as being extractable into organic solvents and the remaining 13% was unaccounted for. In addition, Table 4 indicates that 101.3% of the TRR in liver was characterized. It is not clear, however, what percentage of the liver TRR was lost, since only 44% (Table 3) was soluble and analysis of the remainder was not reported. In kidney, although 93.2% of the TRR is reported as having been characterized, it is not clear whether the remaining 6.8% was lost or represents uncharacterized bound radioactivity (reported in Table 3 as 7% of the TRR).

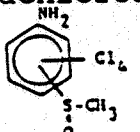
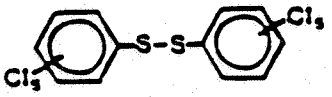
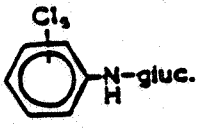
No data on characterization of the TRR of muscle was available for review in the Uniroyal submission; no explanation was given for this omission. However, the registrant noted that liver, kidney, and fat were the only tissues that showed radioactivity above background. We note however, that the above Amvac metabolism study (MRID 41303301) reported a TRR of 0.483 ppm in muscle from the high-dose goat (Table 2). Thus, Uniroyal should indicate if the goat used in the Uniroyal study is the same animal that was dosed with 50 mg/kg in the Amvac study.

Table 4. PCNB and its metabolites.

Code	Chemical name Structure	Substrate	MRID Common name
I.	Pentachloronitrobenzene 	none[a]	41341205 PCNB
II.	Pentachloroaniline sulfamate 	goat urine	41341205 Metabolite II
III.	N-Hydroxypentachloroaniline 	goat liver goat urine	41341205 41341205 Metabolite III
IV.	Tetrachloro(methylthio)thiophenol 	goat liver goat kidney goat urine	41341205 41341205 41341205 Metabolite IV
V.	Pentachloroaniline mercapturic acid conjugate (putative) 	goat urine	41341205 Metabolite V
VI.	Pentachlorothiophenol 	goat kidney	41341205 Metabolite VI
VII.	Tetrachlorothioanisole 	goat liver goat kidney	41341205 41341205 Metabolite VII
VIII.	Pentachloroaniline 	goat liver goat kidney goat omental fat goat renal fat goat milk	41341205 41341205 41341205 41341205 41341205 PCA, Metabolite VIII

(Continued)

Table 4. PCNB and its metabolites (continued).

Code	Chemical name Structure	Substrate	MRID Common name
IX.	Tetrachloroaniline methylsulfoxide 	goat kidney	41341205 Metabolite IX
X.	Pentachlorothiophenol dimer 	goat liver	41341205 Metabolite X
XI.	N-Glucuronide of pentachloroaniline 	goat liver goat kidney	41341205 41341205 Metabolite XI

[a] No unmetabolized PCNB was observed in milk, tissues or urine.

In summary, the metabolites of PCNB in goats are incompletely characterized. Due to incomplete data reporting, levels for metabolites in goat matrices are uncertain. In addition, it is not clear from the available data whether metabolites in muscle should be characterized.

Additional data are required, including: (i) a clarification of whether the goat used in the Uniroyal metabolite characterization study (MRID 41341205) is the same goat dosed at 50 mg/kg of body weight in the Amvac metabolism study (MRID 41303301). If the two goats are different, Uniroyal should submit dosing procedures and other pertinent details of the in-life phase of the study in addition to quantification of the TRR in the various goat matrices. If the two goats are the same, the metabolites in muscle should be characterized; the fraction of the TRR partitioned into each solvent used in the extraction and into bound residue for milk, fat, and liver (and muscle, if warranted by the TRR in muscle); and for each extract that was analyzed by HPLC, provide the amount of radioactivity applied in each HPLC analysis and the amount of radioactivity detected in the identified radioactive zones.

Table 5. Percent distribution of ^{14}C-residues in matrices of a goat administered [^{14}C]PCNB orally.

	Percent distribution of goat metabolites in					
Metabolite[a]	Liver	Kidney	Omental Fat	Renal Fat	Milk	Urine
II	-[b]	-	-	-	-	85.0
III	4.7	-	-	-	-	5.0
IV	1.0	4.5	-	-	-	6.0
V	-	-	-	-	-	4.0
VI	2.9	3.3	-	-	-	-
VII	-	2.1	-	-	-	-
VIII	17.0	26.0	100.0	100.0	96.0	-
IX	-	2.3	-	-	-	-
X	2.7	-	-	-	-	-
XI	73.0	55.0	-	-	-	-
Total:	101.3	93.2	100.0	100.0	96.0	100.0

[a] Metabolite codes and the corresponding chemical names and molecular structures are depicted in Table 4.

[b] - = Not reported.

Poultry. Uniroyal Chemical Co. (1989; MRID 41341204) submitted preliminary data concerning the metabolism of PCNB in chickens. Laying hens were administered [^{14}C]PCNB in the diet for 6 days at

15, 37.5, or 75 mg/day (whether per bird or per kg body weight could not be determined; dietary intake in terms of ppm of residues in the feed was not reported). Eggs and excreta were collected daily and the birds were sacrificed ca. 6 hours after the final dose. Total radioactive residues (TRR) were 10 ppm in abdominal fat, 0.3 ppm in breast muscle, 8.4 ppm in egg yolks, and 0.3 ppm in egg whites from hens dosed at the highest level. TRR in other tissues were not reported nor were data from the lower dosing levels. Tissues were extracted using the Bligh-Dyer technique; the distributions of the ^{14}C-residues in the extracts and unextracted fractions of tissues and egg yolk are depicted in Table 6.

Table 6. Distribution of total tissue ^{14}C-activity in extracts and unextracted fractions.

Tissue	% of TRR in extract/fraction			
	Aqueous	Chloroform	Unextracted	Total
Breast muscle	21.9	31.8	51.3	105.0
Thigh muscle	40.8	70.4	25.9	137.1
Liver	59.0	23.0	35.2	117.2
Fat	4.5	105.9	0.5	110.9
Skin	20.9	76.8	2.5	100.3
Egg yolk	4.9	14.9	75.3	95.1

^{14}C-Residues were isolated using preparatory thin-layer chromatography (TLC) and high-performance liquid chromatography. Pentachlorophenol, pentachlorothiophenol, pentachloroaniline, and pentachlorothioanisole were tentatively identified in organic extracts of liver. Greater than 75% of the unextracted residues in liver were released by protease, although details of the protease digestion step were not reported. Abdominal fat and egg yolk contained residues corresponding to unchanged PCNB, pentachloroaniline, and thioanisole. Five conjugates of pentachlorothiophenol and two of pentachloroaniline were isolated from the aqueous portion of excreta. No details of extraction or hydrolysis procedures, or descriptions of chromatographic methods were presented. Isolated residues were not quantified and no data from confirmatory analyses were submitted. The registrant states that they plan to submit a complete report in 3/90.

Amvac Chemical Corp. (1988; MRID 41303101) submitted data pertaining to residues of [^{14}C]PCNB in poultry tissues and eggs. Uniformly ring-labeled [^{14}C]PCNB (radiochemical purity >98%; specific activity 12.1 mCi/mmol) was mixed with non-labeled PCNB and administered, for 5 consecutive days, to 10 laying hens orally via capsule at 25 and 50 mg/kg of body weight per day, equivalent to a dietary level of 309 and 554 ppm, respectively

(final specific activity, 1.66-3.33 x 10^4 dpm/ug). Eggs were collected twice a day and yolks and whites separated, and excreta was collected once daily. The hens were sacrificed ca. 6 hours after the last dose, and tissues were collected; samples of eggs and tissues were radioassayed by LSS following combustion. Recovery of radioactivity be the radioanalysis procedures was 97-101%.

Excreta contained 65-71% of the total dose. Total radioactive residues (TRR) in egg yolk (collected after the last dose) were 1.22 ppm from the low-dose group and 2.656 ppm from the high dose group; corresponding egg white samples contained 0.017 ppm and 0.038 ppm, respectively. TRR in tissues from hens dosed at low and high levels were, respectively, 1.465 and 1.848 ppm in kidney, 1.973 and 2.415 ppm in liver, 0.127 and 0.145 ppm in thigh muscle, 0.155 and 0.306 ppm in breast muscle, 2.107 and 4.247 ppm in abdominal fat, and 1.124 and 2.181 ppm in skin with fat. The radioactive residues were not extracted or characterized.

RESIDUE ANALYTICAL METHODS

Conclusions:

The PCNB Guidance Document (1/87) requires complete descriptions of analytical methods, including validation data and representative chromatograms, for the detection and quantification of all residues and impurities of concern in or on plant and animal commodities. This requirement remains in effect. It should be noted that the nature of the residue in plants and animals is not adequately understood, and that the adequacy of the existing methodology will be determined following evaluation of the required metabolism studies.

The Pestrak data base dated 12/13/89 indicates that PCNB is completely recovered (>80%) using Multiresidue Protocol E (both fatty and non-fatty food methods) and Protocol D. The metabolites PCA and MPCPS and the impurity PCB are completely recovered (>80%) using the fatty and non-fatty food methods of Protocol E; HCB is completely recovered from non-fatty foods and partially recovered (50-80%) from fatty foods using Protocol E. PCNB metabolites and impurities must be subjected to analyses using Protocols C and D; therefore, the following additional data are required:

- Data depicting the recovery of PCA, MPCPS, PCB, and HCB using FDA Multiresidue Protocols C and D, published in Pesticide Analytical Manual (PAM) Vol. I and available from the National Technical Information Service (NTIS) under order No. PB 203734/AS.

- The nature of the residue in plants and animals is not adequately understood. If the metabolism studies requested in the sections "Qualitative Nature of the Residue in Plants" and "Qualitative Nature of the Residue in Animals" reveal the presence of additional metabolites of concern, additional validated methods for data collection and tolerance enforcement will be required.

STORAGE STABILITY DATA

Conclusions:

The PCNB Guidance Document (1/87) requires data depicting the storage stability of PCNB, PCA, MPCPS, PCB, and HCB in all animal and plant raw agricultural commodities for which tolerances are proposed. Also required are data depicting the intervals and conditions of sample storage to validate the residue data submitted in support of established or interim tolerances for residues in or potatoes, a brassica leafy vegetable, beans, peppers, tomatoes, cottonseed, and peanuts, and their processed commodities, as well as supporting data depicting the storage stability of PCNB per se. Furthermore, it was specified that all residue data required by the Guidance Document be accompanied by data regarding the length and conditions of sample storage and supporting storage stability data.

In response to the Guidance Document, Uniroyal Chemical Co. (1988; MRIDs 40921600 and 40921601) submitted data pertaining to the storage stability of PCNB, PCA, MPCPS, PCB, and HCB in or on wheat, corn, soybeans, kidney beans, peppers, tomatoes, tomato catsup, and tomato pomace. In an Agency review (M. Flood, DEB No. 4751, 1/29/89), it is concluded that, for those commodities included in the study, correction factors should be applied to all residue values where decline over 6 months exceeds 20%; this category includes corn grain, soybeans, peppers, and tomatoes. For crops for which no storage stability data are available, additional decline data are required unless samples are analyzed within 2 weeks of harvest. Since the data failed to show any pattern of residue decline in related crops, additional data on all pertinent commodities are required.

No data were submitted on the intervals and conditions of residue sample storage called for in the Guidance Document, nor were there any data on the storage stability of residues in animal commodities. The following additional data are required:

- The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for plant and animal commodities. Storage stability data on PCNB and residues of concern in support of previously submitted residue data are required for

only those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of PCNB residues of concern in commodities stored under the range of conditions and for the range in intervals specified. Crop samples bearing measurable weathered residues or fortified with PCNB residues of concern and fortified meat and milk samples must be analyzed immediately after harvest or fortification and again after storage intervals that allow for reasonable unforseen delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field weathered samples are used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the registrant is referred to an August, 1987 Position Document on the Effects of Storage Validity of Pesticide Residue Data available from NTIS under order no. PB 88112362/AS.

The nature of the residue in plants and animals is not adequately understood. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting stability of these residues during storage will be required.

References (used):

MRIDs: 40921600. 40921601.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN PLANTS

Decisions as to the adequacy of established tolerances have been based upon evaluation of the existing data base, including data reviewed for the PCNB Guidance Document dated 1/87 and recently submitted data discussed in Agency reviews. It should be noted that the conclusions stated in this section regarding the adequacy of the established tolerances may change following the submission and review of the required data on plant metabolism and storage stability. The registrant should be urged to complete and submit all required plant metabolism studies prior to initiation of required field trials and processing studies.

The PCNB Guidance Document dated 1/87 identifies outstanding data requirements on potatoes, broccoli, cabbage, lima beans, snap beans, dry beans, peppers, tomatoes, bananas, cottonseed, and

peanuts. Processing studies are required for potatoes, beans, tomatoes, cottonseed, peanuts, and soybeans.

The Guidance Document also noted the need for data reflecting uses permitted by intrastate registrations and required that tolerances be proposed for residues in or on the appropriate commodities. The following requirements remain outstanding:

- Tolerances must be proposed for PCNB residues of concern in or on lettuce, strawberries, alfalfa forage, alfalfa hay, clover forage, and clover hay, and submit appropriate supporting residue data. Alternatively, the registrant may elect to cancel these uses permitted under AZ State Reg. No. N, CA State Reg. Nos. 10972-50043 AA and 10972-50199 AA, and TX State Reg. No. 74.

Data on crops with only seed treatments reviewed for the Guidance Document indicate that soybean plants grown from treated seed bore finite residues of PCNB per se. Thus, tolerance proposals for PCNB residues of concern in or on soybean forage and hay are required along with supporting residue data. Data depicting the potential for uptake and translocation of residues by corn, peas, rice, safflower, sugar beets, and wheat grown from [^{14}C]PCNB-treated seed are required in order to evaluate the non-food status of these seed-treatment-only uses.

The Guidance Document also required numerous label amendments and clarifications. The following requirements remain outstanding:

- The registrant must amend all pertinent product labels to specify a maximum single application rate (expressed in lb ai/A) and a maximum seasonal rate or number of applications per season; a minimum interval between applications and a PHI must also be specified. The requested data must reflect these specifications.

Since the issuance of the Guidance Document, tolerances with regional registration have been established for residues of PCNB and its metabolites pentachloroanaline (PCA) and methyl pentachlorophenyl sulfide (MPCPS) in or on collards, kale, and mustard greens.

Recently submitted data on storage stability reveal that residues of PCNB and metabolites decline over 20% in corn grain, soybeans, peppers, and tomatoes after 6 months in frozen storage and that decline data are required for all other commodities stored for longer than 2 weeks prior to analysis. The registrant has been instructed to apply correction factors to pertinent residue values based on the decline data for the commodity in question.

It should be noted that the requirements for field trial locations specified in the Guidance Document were based on

Agricultural Statistics, 1984, or 1982 Census of Agriculture, Vol. 1, Part 51. Some of the geographic requirements specified in this review are based on the more recent statistics from the Agricultural Statistics Board, NASS, USDA; Crops Database and Vegetables Summary.

Root and Tuber Vegetables Group

Potatoes

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on potatoes (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on potatoes (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on potatoes following preplant broadcast application of G, WP, and EC formulations at 25 lb ai/A and an in-furrow at planting application using these same formulations each at 11.7 lb ai/A. [We note that the updated EPA Index to Pesticide Chemicals dated 3/89 lists the maximum rate for in-furrow application as 10 lb ai/A.] In response to these requirements, Uniroyal Chemical Co. has submitted one volume of data (1988; MRID 40816701) reflecting broadcast and in-furrow applications of an EC formulation; these data are currently under review by the Agency (R. Perfetti, personal communication, 11/20/89). Two other volumes of data regarding potatoes have been submitted; however, these data are not useful for assessing the established or proposed tolerance because information concerning the location and methods of field application and analytical methodology were not provided (MRIDs 40866014 and 40866015). The following data requirements remain outstanding:

- Data depicting PCNB residues of concern in or on potatoes following preplant broadcast application using a representative G, EC, and WP formulation at 25 lb ai/A and an in-furrow at planting application using these same formulations each at 10 lb ai/A. The tests must be conducted in ID(26%), OR(7%) or WA(17%), CA(5%), MI(3%) or WI(6%), MN(5%) or ND(6%), ME(6%), and FL(2%), since these states represent the major U.S. potato-growing regions accounting for ca. 80% of U.S. production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

In addition, the PCNB Guidance Document dated 1/87 requires data on potato chips, granules, and flakes processed from potatoes treated in-furrow at 50 lb ai/A (ca. 5x) in order to obtain measurable weathered residues. In response to this requirement, Uniroyal Chemical Co. submitted potato processing data (1986-1987; MRIDs 40070401 and 40088401) which were reviewed by the Agency and found insufficient to satisfy data requirements because the specified protocol was not followed (L. Cheng, DEB Nos. 1890, 1891, and 1923 dated 2/24/87 and 1965 dated 3/10/78). Additional data were submitted (1987; MRID 40457401) and the Agency concluded that no food or feed additive tolerance is required for processed potato chips, flakes, or granules (N. Gray, DEB No. 3169, 5/17/88). It was noted that since the issuance of the Guidance Document, the requirements for potato processing have been revised to include wet and dry peel, and that additional data on these commodities are required. The review stipulated that the required processing study on wet and dry peel be conducted using formulations representative of technical PCNB containing <0.1% HCB, and that the methodology used be capable of detecting HCB at 0.001 ppm. The registrant then submitted a protocol for the required study which was approved providing that the analytical methodology used would be the same as that used in the previous study (MRID 40457401) and that PCNB would be applied at least 5x the maximum registered rate (M. Flood, DEB No. 4752, 1/10/89). Until these data are received, the following requirement remains outstanding:

- Data depicting the potential for residue concentration of PCNB residues of concern in wet and dry peel processed from potatoes treated at at least 5x the maximum registered rate bearing measurable weathered residues. The formulation(s) used must represent technical PCNB containing <0.1% HCB. Samples must be analyzed using the same methodology as in the previous study (MRID 40457401) validated at 0.001 ppm for HCB. If residues concentrate in either commodity, an appropriate feed additive tolerance will be required.

The Agency has determined that residues of PCNB and metabolites and impurities are likely to exceed 0.1 ppm, based on data on whole potatoes in MRID 40457401 and data currently under review.

References (used):

MRIDs: 40070401. 40088401. 40457401. 40816701.

References (not used):

[The following references do not contain sufficient information to allow evaluation of the data therein.]

MRIDs: 40866014. 40866015.

[The following reference contains data reviewed for the PCNB Guidance Document.]

MRID: 00159016.

Discussion of the data:

N/A.

Bulb Vegetables Group

Garlic

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on garlic (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on garlic (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires the product labeling for in-furrow treatment be amended to specify the spray band width as well as the number of row-feet per field acre. The updated EPA Index to Pesticide Chemicals dated 3/89 lists no such specifications. The following requirement remains outstanding:

- All product labels bearing directions for in-furrow application to garlic must be amended to specify both the spray band width and the number of row-feet per acre.

References (used):

N/A.

Discussion of the data:

N/A.

Brassica Leafy Vegetables Group

Broccoli

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on broccoli (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on broccoli (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on broccoli following pre-transplanting broadcast soil application of the 10% G and 75% WP formulations at 60 lb ai/A followed by at-transplanting application at 40 lb ai/A. Data are also required reflecting at-transplant application at 60 lb ai/A. In response to these requirements, Uniroyal Chemical Co. has submitted one volume of data reflecting broadcast, band, and transplant applications using the 10% G and 75% WP formulations (1988; MRID 40816702); these data are currently under review by the Agency (R. Perfetti, personal communication, 11/20/89). Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding:

- Data depicting PCNB residues of concern in or on broccoli resulting from pre-transplanting broadcast incorporated soil application of the 10% G and 75% WP formulations at 60 lb ai/A followed by at-transplanting application at 40 lb ai/A (13,000 row-feet) incorporated into a 14-inch band. Data are also required reflecting at-transplant application at 60 lb ai/A in a transplant solution. Tests must be conducted in CA (90%) and TX(5%) since these states accounted for ca. 95% of the 1986 U.S. broccoli production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87).

References (used):

MRID: 40816702.

Discussion of the data:

N/A.

Brussels Sprouts

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on Brussels sprouts (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on Brussels sprouts (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 concludes that the data required for broccoli will, by translation, satisfy the requirement for data on Brussels sprouts.

References (used):

N/A.

Discussion of the data:

N/A.

Cabbage

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on cabbage (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on cabbage (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on cabbage following pre-

transplanting broadcast soil application of the 10% G and 75% WP formulations at 60 lb ai/A followed by at-transplanting application at 40 lb ai/A. Data are also required reflecting at-transplant application at 60 lb ai/A. In response to these requirements, Uniroyal Chemical Co. has submitted one volume of data reflecting broadcast, band, and drench applications using the 10% G and 75% WP formulations (1988; MRID 40816703); these data are currently under review by the Agency (R. Perfetti, personal communication, 11/20/89). Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding:

- Data depicting PCNB residues of concern in or on cabbage resulting from pre-transplanting broadcast incorporated soil application of the 10% G and 75% WP formulations at 60 lb ai/A followed by at-transplanting application at 40 lb ai/A (13,000 row-feet) incorporated into a 14-inch band. Data are also required reflecting at-transplant application at 60 lb ai/A in a transplant solution. Tests must be conducted in CA(8%), FL(16%), NY(15%), NC(5%), TX(16%), and WI(9%) since these states accounted for ca. 70% of the 1986 U.S. cabbage production (1982 Census of Agriculture, Vol. I, Part 51, p. 338).

References (used):

MRID: 40816703.

Discussion of the data:

N/A.

Cauliflower

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on cauliflower (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on cauliflower (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 concludes that the data required for broccoli will, by translation, satisfy the requirement for data on cauliflower.

References (used):

N/A.

Discussion of the data:

N/A.

Collards, kale, and mustard greens

Tolerance(s):

Tolerances with regional registration of 0.2 ppm have been established for the combined residues of PCNB and its metabolites PCA and MPCPS in or on collards, kale, and mustard greens (40 CFR 180.291[b]).

Conclusions:

At the time of the issuance of the PCNB Guidance Document dated 1/87, no tolerance was established for residues of PCNB in or on collards, kale, or mustard greens. In the Agency review of data submitted in support of the current tolerance (MRID 00158795), it was concluded that a tolerance of 0.2 ppm for the combined residues of PCNB, its metabolites PCA and MPCPS, and the impurities PCB and HCB (of which not more than 0.02 ppm is HCB) is appropriate, providing that the use is restricted to GA (W. Chin, DEB Nos. 897 and 1069; 7/17/86). Subsequently, it was concluded that PCB and HCB need not be included in the tolerance definition, since the data indicate that these residues were <0.01 ppm (nondetectable) in or on collard greens (W. Chin, DEB No. 2131; 5/6/87).

References (used):

MRID: 00158795.

Discussion of the data:

N/A.

Legume Vegetables Group

Beans (succulent and dried)

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on beans (40 CFR 180.319). A tolerance of 0.2 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on beans (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on snap, lima, and dry beans following four applications totalling 7.5 lb ai/A using a D, EC, and WP formulations. Data on cannery waste were also required. The updated Index to Pesticide Chemicals dated 3/89 lists only EC and WP formulations for these uses. In response to these requirements, Uniroyal Chemical Co. has submitted one volume of data reflecting applications of EC and WP formulations to snap, lima, and dry beans (1988; MRID 40816704); these data are currently under review by the Agency (R. Perfetti, personal communication, 11/20/89). Additional submissions contain data reviewed previously for the guidance document (MRIDs 40866004, 40866005, and 40866006) or contain data that are not useful because no details of the field trial were provided and the variety of beans tested was not specified (MRID 00165640).

Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding:

- Data depicting PCNB residues of concern in or on snap, lima, and dry beans, and bean vines and hay following four applications of the 75% WP and 2 lb/gal EC formulations; the first application should be made at 1.5 lb ai/A and the subsequent applications must be made at 14-day intervals at 2 lb ai/A. The tests on dry beans must be conducted in CA(12%), CO(10%), ID(11%), MI(21%), NE(13%), and ND(19%); tests on snap beans must be conducted in NY(10%), OR(23%), and WI(41%); and tests on lima beans must be conducted in CA. [Production data in parentheses were obtained from Agricultural Statistics Board, NASS, USDA; 1986 Vegetables Summary.] Based on the residue data, tolerances must be established for PCNB residues of concern in or on bean vines and hay; alternatively, the registrant may propose to add amend

the pertinent product labels to include a feeding restriction.

- Data depicting the potential for concentration of PCNB residues of concern in cannery waste processed from beans bearing measurable weathered residues. If residues concentrate in this commodity, an appropriate feed additive tolerance must be proposed. A tolerance for residues in or on bean vines and hay supported by adequate residue data may substitute for the requirement for a processing study on cannery waste.

References (used):

MRID: 40816704.

References (not used):

MRIDs: 00165640. 40866004. 40866005. 40866006.

Discussion of the data:

N/A.

Fruiting Vegetables (Except Cucurbits) Group

Peppers

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on peppers (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on peppers (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on peppers following in-furrow transplant applications of the 75% WP formulation at 7.5 lb ai/A and in a transplant solution at 34 lb ai/A. In response to these requirements, Uniroyal Chemical Co. has submitted one volume of data reflecting in-furrow and transplant solution applications (1988; MRID 40816705); these data are currently under review by the Agency (R. Perfetti, personal communication, 11/20/89). Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding:

- Data depicting PCNB residues of concern in or on peppers resulting from in-furrow transplant applications of the 75% WP formulation at 7.5 lb ai/A and in a transplant solution at 34 lb ai/A. Tests must be conducted in CA(18%), FL(23%), NC(10%), and TX(16%), since these states accounted for ca. 70% of the 1986 U.S. sweet pepper production (1982 Census of Agriculture, Vol. I, Part 51, p. 350).

References (used):

MRID: 40816705.

Discussion of the data:

N/A.

Tomatoes

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on tomatoes (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on tomatoes (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on tomatoes following in-furrow transplant applications of the 75% WP formulation at 7.5 lb ai/A and in a transplant solution at 25.5 lb ai/A. In addition, data on the processed commodities of tomatoes were required. One volume of data was submitted (1978; MRID 40866016); however, the reference contained no residue or processing data. The following requirements remain outstanding:

- Data depicting PCNB residues of concern in or on tomatoes resulting from in-furrow transplant applications of the 75% WP formulation at 7.5 lb ai/A and in a transplant solution at 25.5 lb ai/A. Tests must be conducted in CA(77%), FL(9%), and IN(2%), MI(2%), or OH(5%), since these states accounted for ca. 95% of the 1986 U.S. tomato production (Agricultural Statistics Board, NASS, USDA, 1987, Vegetables, 1986 Summary, pp. 16 and 53).

- Data depicting the potential for concentration of PCNB residues of concern in juice, puree, catsup, and dry

pomace processed from tomatoes bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food or feed additive tolerance must be proposed.

References (used):

N/A.

References (not used):

MRID: 40866016.

Discussion of the data:

N/A.

Miscellaneous Commodities

Bananas

Tolerance(s):

An interim tolerance of 0.1 ppm is in effect for residues of PCNB per se in or on bananas (40 CFR 180.319). A tolerance of 0.1 ppm (not more than 0.02 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on bananas (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on bananas treated using the 1.63% RTU formulation as a dip. It was noted that residues appeared to concentrate during shipment and, therefore, sampling of bananas after treatment and after arrival in the U.S. should be required. No data have been submitted in response to the Guidance Document; therefore, the following data requirements remain outstanding:

- Data depicting PCNB residues of concern in or on bananas treated using the 1.63% RTU formulation at 1 gallon of product/700-800 stems. The stems should be dipped at the butt and tip end and the remainder of the dose brushed onto cuts and scrapes along the stems. Whole bananas must be sampled immediately after treatment and again after arrival at the U.S. port of entry following intercontinental shipment under representative transport conditions; the data must reflect minimum and maximum anticipated shipment intervals. In addition, copies of the labels for all PCNB products currently used in

countries that export bananas to the U.S. must be submitted.

References (used):

N/A.

Discussion of the data:

N/A.

Cottonseed

Tolerance(s):

A tolerance of 0.1 ppm has been established for residues of PCNB per se in or on cottonseed (40 CFR 180.291[a]).

Use directions and limitations:

The 2/22/89 update of the Index to Pesticide Chemicals identifies various single and multiple active ingredient formulations of PCNB registered for use on cottonseed as: (i) seed treatments in the form of dust, liquid, or slurry; (ii) planter box-delivered seed/soil treatments; and (iii) in-furrow and seed bed treatments.

Seed treatments: The 10-30% D, 20% WP, 2 lb/gal EC, 1.72-1.89 lb/gal FlC, and 1.7-2 lb/gal RTU formulations may be applied at 0.1-0.3 lb/cwt.

Planter box-delivered seed/soil treatments: The 10-30% D formulations are registered for use at 0.3-1 lb ai/A and the 10% G formulation may be applied at 0.3 lb ai/A.

In-furrow and seed bed treatments at planting: The 5-10% G formulations are registered for use at 0.5-5 lb ai/A and the 2 lb/gal EC and 30-70% WP formulations are registered for application at 0.325-2 lb ai/A as an open furrow (over seed) treatment at planting time.

Treated cotton forage may not be grazed by or fed to livestock. The feeding of gin trash from treated cotton is restricted. No PHI has been established.

Conclusions:

The PCNB Guidance Document dated 1/87 concludes that the established tolerance is inadequate, since tolerance exceeding residues were detected in or on cottonseed treated at 0.5x the maximum registered rate. However, it was concluded that the available data were insufficient to determine an appropriate tolerance level, and data are required reflecting in-furrow and surface band application made at planting to cotton using representative G, WP, and EC formulations. Also, the Guidance Document noted that the data available data on processing of cottonseed indicate that residues concentrate 6x in crude oil and that no concentration occurs in meal; however, since no data were available on hulls, refined oil, and soapstock, it was concluded that additional processing data are required.

The data submitted in response to the Guidance Document (MRID 41341206) reflect application of an EC formulation at 1x, although the G formulation was applied at only 0.4x the maximum registered rate of 5 lb ai/A. No data were submitted reflecting application of a WP formulation. The residues of PCNB in or on cottonseed used in the processing study (treated with a G formulation at 10 lb ai/A, or 2x the maximum registered rate) were detectable in only one sample at 0.005 ppm (the limit of detection), and the untreated sample from that test bore residues of 0.008 ppm. PCNB residues in oil were 0.022-0.024 ppm, up to 5x the level in seed, but the oil from untreated samples contained residues of 0.026-0.03 ppm. In order to adequately assess the potential for concentration of residues during processing, additional data are needed reflecting detectable residues resulting from treatment at an exaggerated rate >2x. Therefore, the following additional data are required:

- Data depicting PCNB residues of concern in or on cottonseed resulting from in-furrow and surface band over-the row applications made at-planting using a representative G formulation at 5 lb ai/A and a WP formulation at 2 lb ai/A. Tests must be conducted in AZ(7%), CA(20%), LA(7%), MS(12%), and TX(32%), since these states accounted for ca. 80% of the 1987 U.S. cotton production (Agricultural Statistics Board, NASS, USDA, Crop Database, Jan, 1988).

- Data depicting the potential for concentration of PCNB residues of concern in hulls, refined oil, and soapstock processed from cottonseed bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food or feed additive tolerance must be proposed. If the requested plant metabolism data reveal residues of concern other than PCNB, PCA, MPCPS, PCB, and HCB, additional processing data on meal and crude oil will be required.

References (used):

MRIDs: 41341206.

Discussion of the data:

Uniroyal Chemical Company, Inc. (1989; MRID 41341206) submitted data from 20 tests conducted in AZ(8), LA(8), and MS(4) depicting residues of PCNB and its metabolites and impurities of concern (PCB, HCB, PCNB, PCA, and pentachlorothioanisole or PCTA) in or on cottonseed harvested at maturity (137-175 days posttreatment) following an in-furrow application at planting of the 2 lb/gal EC and 10% G formulations at 2 lb ai/A (1x the maximum rate for an EC formulation and 0.4x that for a G formulation). Residues in or on 20 samples of cottonseed were: (i) <0.005(nondetectable)-0.012 ppm for PCNB; (ii) <0.005 ppm (nondetectable) each for PCB, HCB, and PCTA; and (iii) <0.005(nondetectable)-0.007 ppm for PCA. Apparent residues <0.005(nondetectable)-0.005 in or on 10 control samples. Data were collected using a GLC/EC method (Method No. CAM-24-73) which is similar to Method I in PAM Vol. II. The limit of detection was 0.005 ppm. Following fortification of 10 samples with each compound at 0.005-0.05 ppm, recoveries were: (i) 90-116% for PCNB; (ii) 76-100% for PCB; (iii) 78-95% for HCB; (iv) 90-110% for PCA; and (v) 89-110% for PCTA. Samples were stored frozen for ca. 169-577 days prior to analysis.

The same submission contained data from a cottonseed processing study. In two tests conducted in MS, cottonseed was harvested at maturity (149 days posttreatment) following an in-furrow application at planting of the 10% G formulation at 10 lb ai/A (2x the maximum registered rate). Residues in or on two samples of cottonseed were <0.005 ppm (nondetectable) for PCB, HCB, PCA, and PCTA; residues of PCNB were <0.005 (nondetectable) -0.005 ppm. Residues of PCNB were 0.022 ppm in refined oil, 0.024 ppm in crude oil, and were <0.005 ppm (nondetectable) in soapstock, reclaimed solvent, hulls, and meal. Residues of PCA (one sample per fraction) were 0.006 ppm in refined oil, soapstock, and crude oil, and were <0.005 ppm (nondetectable) in reclaimed solvent, hulls, and meal. Residues of PCB, HCB, and PCTA (one sample per fraction) were <0.005 ppm (nondetectable) in refined oil, soapstock, crude oil, reclaimed solvent, hulls, and meal. Apparent residues of PCNB in or on control samples (one sample per fraction) were 0.026 ppm in refined oil, 0.030 ppm in crude oil, 0.005 ppm in hull, and <0.005 ppm (nondetectable) in reclaimed solvent and meal. Apparent residues of PCA in or on control samples (one sample per fraction) were 0.006 ppm in refined oil, soapstock, and crude oil, and were <0.005 ppm (nondetectable) in reclaimed solvent, hulls and meal. Apparent residues of PCB, HCB, and PCTA in control samples (one sample per fraction) were <0.005 ppm (nondetectable) each in refined oil, soapstock, crude oil, reclaimed solvent, hulls, and meal. Data

were collected using a GLC/EC method (Method No. CAM-24-73) similar to the GLC/EC method listed in PAM Vol. II as Method I. The limit of detection was stated as 0.005 ppm for each compound, although we note that some control samples of seed, crude oil, and refined oil bore apparent PCNB residues greater than 0.005 ppm. Recovery of PCNB was 92-116% from cottonseed samples fortified at 0.005-0.05 ppm, 98% from soapstock fortified at 0.05 ppm, 132% from refined oil fortified at 0.005 ppm, 95% from crude oil fortified at 0.02 ppm, 80% from hulls fortified at 0.05 ppm, and 84% from meal fortified at 0.05 ppm. Recovery of PCB, HCB, PCA, and PCTA was 70-110% from cottonseed processed commodities fortified at 0.005-0.05 ppm. Samples were stored frozen for unreported intervals prior to analysis.

Geographic representation of the data is adequate since the test states of AZ(7%), LA(7%), and MS(12%) along with the neighboring states of TX(32%), and CA(20%) represent ca. 78% of the U.S. cotton production (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988). However, the available residue data do not reflect current maximum registered use pattern of PCNB in cottonseed because the G formulation was not applied at 1x the maximum registered rate and no data were submitted reflecting registered use of a WP formulation. Furthermore, the processing study is inadequate since residue levels in or on cottonseed were not high enough to assess the potential for concentration of residues. Additional data are required.

Peanuts

Tolerance(s):

An interim tolerance of 1 ppm is in effect for residues of PCNB per se in or on peanuts (40 CFR 180.319). A tolerance of 2 ppm (not more than 0.4 ppm of which is HCB) has been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in or on peanuts, and a tolerance of 5 ppm (not more than 0.3 ppm of which is HCB) has been established for these same residues in or on peanut hulls (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 requires data depicting PCNB residues of concern in or on peanuts and peanut hulls harvested 45 days following surface-banded application made at pegging using the 30% G and 75% WP formulations. Data are also required to support SLN registrations permitting at-pegging application by overhead sprinkler (AL, GA, OK, and TX) and using aerial equipment (TX). In addition, data on processed commodities of peanuts are required.

Uniroyal Chemical Co. has submitted one volume of data from tests using an EC and a FlC formulation applied with overhead irrigation equipment in GA, OK, and VA (1988; MRID 41002507). The data were submitted in support of a request for an experimental-use permit for the new FlC formulation, and were reviewed in that context by the Agency (L. Propst, DEB No. 5217; 5/8/89). The data for the EC formulation indicate that combined residues of PCNB, PCA, MPCPS, PCB, and HCB were <0.025(nondetectable)-<0.028 ppm in or on three samples from VA and <0.335-1.146 ppm in or on four samples from GA (the data from OK are disregarded due to apparent contamination of plants from untreated plots); the combined residues in or on the GA and VA samples included HCB residues of <0.005(nondetectable)-0.0061 ppm. With respect to the requirements in the Guidance Document, these data do not satisfy the requirement for soil applications, aerial applications, or overhead sprinkler applications in OK or TX. The data indicate that application of an EC formulation by overhead sprinkler in GA (EPA SLN No. GA810003) and AL (AL800010) is not likely to result in tolerance-exceeding residues.

Additional data from field trials on peanuts were submitted (1977; MRID 40866012), but are not useful for tolerance assessment because application was made >150 days before harvest, the formulation used was not specified, and the method of application was not reported. Three volumes containing processing data were submitted (MRIDs 00165639, 40866011, and 40866013) but are disregarded because spiked samples were used and no commodities of interest were analyzed.

The following requirements remain outstanding:

- Data depicting PCNB residues of concern in or on peanut nutmeats and hulls harvested 45 days following surface-banded application made at pegging using the 30% G and 75% WP formulations each at 10 lb ai/A in separate tests. Tests must be conducted in AL(13%) or GA(44%), NC(11%) or VA(6%), and OK(6%) or TX(12%), since these states accounted for ca. 80% of the 1987 U.S. cotton production (Agricultural Statistics Board, NASS, USDA, Crop Database, Jan, 1988).

- Data depicting PCNB residues of concern in or on peanut nutmeats and hulls harvested 45 days following overhead sprinkler application of the 75% WP and 2 lb/gal EC formulations at 10 lb ai/A, made at pegging. The tests must be conducted in TX to represent the states where this use is permitted. Alternatively, the registrant may elect to cancel these uses permitted under EPA SLN Nos. OK840008, TX790017, and TX840015.

- Data depicting PCNB residues of concern in or on peanut nutmeats and hulls harvested 45 days following aerial

application of the 10% G formulation at 10 lb ai/A made at pegging. The test must be conducted in TX where this use is permitted. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. TX780043.

- Data depicting the potential for concentration of PCNB residues of concern in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food or feed additive tolerance must be proposed. If the requested plant metabolism data reveal residues of concern other than PCNB, PCA, MPCPS, PCB, and HCB, additional processing data on meal and crude oil will be required.

References (used):

MRIDs: 41002507.

References (not used):

MRIDs: 00165639. 40866011. 40866012. 40866013.

Discussion of the data:

N/A.

Crops with Seed Treatments Only

The PCNB Guidance Document dated 1/87 concludes that, since finite residues of PCNB per se were detected in or on leaves from soybeans grown from PCNB-treated seed, seed treatment of soybeans must be considered a food use. It is required that tolerances be proposed for PCNB residues of concern in or on soybeans and soybean forage and hay and that supporting residue data be submitted. The Guidance Document also requires data depicting the uptake and translocation of residues into the food and feed commodities of corn, peas, rice, safflower, sugar beets, and wheat grown from seed treated with [^{14}C]PCNB at the maximum registered seed treatment rate for each crop. In response to the Guidance Document, data were submitted indicating that commodities of corn, peas, sugar beets, soybeans, and wheat grown from treated seed bore detectable residues (1988; MRID 40862901). The Agency has determined that seed treatments using PCNB should not be categorized as non-food uses and that tolerances must be proposed for PCNB residues of concern in or on commodities of these crops (M. Flood, DEB No. 4770; 1/24/89). It was noted that, after the nature of the residue in plants is adequately elucidated, field trials should be conducted to support the proposed tolerances. The Agency review also determined that

processing studies would not be required on corn and soybeans if application at 28 and 5.4x the maximum registered rates, respectively, resulted in no detectable residues in or on corn grain or soybean seed; residues are not expected to concentrate during the processing of non-fatty commodities such as sugar beets and wheat.

The following additional data are required:

- The registrant must propose tolerances for PCNB residues of concern in or on corn grain, forage, and fodder grown from seed treated using a representative D and an EC or RTU formulation at 0.046 lb ai/100 lb of seed. In one test for each formulation, seed should be treated at 1.29 lb ai/100 lb of seed (28x); if no detectable residues result in grain, a processing study will not be required. The tests must be conducted in CO(2%), GA(1%), IL(17%), IA(18%), NE(11%) and TX(2%), since these states accounted for ca. 50% of 1987 U.S. corn grain production and represent the major U.S. corn-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

- The registrant must propose tolerances for PCNB residues of concern in or on soybean seed, forage, and hay grown from seed treated using a representative D and an EC or RTU formulation at 0.105 lb ai/100 lb of seed. In one test for each formulation, seed should be treated at 0.57 lb ai/100 lb of seed (5.4x); if no detectable residues result in soybeans, a processing study will not be required. The tests must be conducted in IA(18%), LA(2%), MN(10%), MO(8%), OH(8%), and TN(2%), since these states accounted for ca. 50% of 1987 U.S. soybean production and represent the major U.S. soybean-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

- The registrant must propose tolerances for PCNB residues of concern in or on peas (succulent and dried), vines, and hay grown from seed treated using a representative D and an EC or RTU formulation at 0.105 lb ai/100 lb of seed. The tests must be conducted in DE(succulent, 4%), ID(dry, 37%), MI(succulent, 23%), NY(succulent, 4%), WA(dry, 63%; succulent, 20%), and WI(28%), since these states accounted for virtually all of the 1987 U.S. production of succulent and dry peas (Agricultural Statistics Board, NASS, USDA, 1987-1988; Crops Database, 1/88, and Vegetables, 1986 Summary).

- The registrant must propose tolerances for PCNB residues of concern in or on sugar beet roots and tops grown from seed treated using representative D, EC, and F1C

formulations at 0.25 lb ai/100 lb of seed. The tests must be conducted in CA(22%), CO(3%), ID(15%), MI(10%), MN(22%), and OR(2%), since these states accounted for ca. 70% of 1987 U.S. sugar beet production and represent the major U.S. sugar beet-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

- The registrant must propose tolerances for PCNB residues of concern in or on wheat grain, forage, hay, and straw grown from seed treated using a representative D formulation at 0.062 lb ai/bu and a representative EC or RTU formulation at 0.053 lb ai/100 lb of seed. The tests must be conducted in CA(2%), CO(5%), KS(17%), OK(6%), TX(5%), and WA(5%), since these states accounted for ca. 40% of 1987 U.S. wheat production and represent the major U.S. wheat-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

References (used):

MRID: 40862901.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN MEAT, MILK, POULTRY, AND EGGS

Tolerances:

Tolerances of 0.05, 0.15, and 0.05 ppm, respectively, (not more than 0.02, 0.05, and 0.02 ppm of which is HCB) have been proposed for residues of PCNB, its metabolites PCA and MPCPS, and impurities PCB and HCB in the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep; tolerances of 0.05 ppm (not more than 0.02 ppm of which is HCB) have been proposed for these same residues in milk and eggs (PP#1F1083, Amendment of 1/83).

Conclusions:

The PCNB Guidance Document dated 1/87 concludes that the adequacy of the proposed tolerances for residues in animal commodities, the need for tolerances for poultry tissues, and the sufficiency of the supporting data will be assessed following receipt and review of the data requested for plant and animal metabolism and residues on livestock feed items.

In an Agency review of data on processed potatoes (DEB No. 3169, 5/17/88), N. Gray recommended that the following tolerances

(expressed as PCNB, PCA, and HCB) be proposed to cover residues from the feeding of potato waste to livestock: (i) 0.05 ppm in poultry fat; (ii) 0.02 ppm in animal and poultry tissues; (iii) 0.03 ppm in milk fat (representing 0.0012 ppm in whole milk); and (iv) 0.01 ppm in eggs. When the outstanding data requirements for plant and animal metabolism, storage stability data, and residues in or on feed commodities have been fulfilled, the need for and nature of tolerances for residues in animal commodities will be determined.

References (used):

N/A.

Discussion of the data:

N/A.

MASTER RECORD IDENTIFICATION NUMBERS

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40457401 Ball, J. (1987) Magnitude of the Residue Terraclor Residues in Processed Potatoes. Unpublished compilation prepared in cooperation with Michigan State Univ. and Morse Laboratories, Inc. 689 p.

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40816702 Ball, J. (1988) Magnitude of the Residue: Terraclor and Its Metabolites in Broccoli: Uniroyal Report No. UR-1408. Unpublished study prepared by Morse Laboratories, Inc. in cooperation with Pan-Agricultural Laboratory and Collins Agricultural Consultants, Inc. 141 p.

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40816704 Ball, J. (1988) Magnitude of the Residue: Terraclor and Its Metabolites in Beans: HAS A026001C: Uniroyal Study No. UR-1409. Unpublished study prepared by Huntingdon Analytical Services. 225 p.

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40862901 Selman, F.; Feutz, E.; Leak, T. (1988) Determining the Uptake and Translocation of [carbon 14] PCNB Used in the Seed Treatment of Corn (Zea mays), Wheat (Triticum aestivum), Soybean (Glycine max), Peas (Pisum sativum), and Sugarbeets (Beta vulgaris): ABC Preliminary Report No. 35972. Unpublished study prepared by Analytical Biochemistry Laboratories, Inc. 43 p.

40921601 Ball, J. (1988) Stability of Terraclor and Allied Metabolites in Frozen Wheat, Corn, Soybeans, Kidney Beans, Peppers, Tomatoes, Catsup, and Dry Tomato Pomace: Project ID. 6012-198A. Unpublished study prepared by Hazleton Laboratories America and Huntingdon Analytical Service. 329 p.

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41303101 Cheng, T. (1989), ^{14}C-PCNB: Nature of the Residue in Livestock - Laying Hens: Lab Project Number 6274/104. Unpiblished study prepared by Hazelton Laboratories America, Inc. 75 p.

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41341201 McManus, J. (1989) PCNB: Nature of the Residue in Potatoes (Progress Report): Lab Project Number: 8760. Unpublished study prepared by Uniroyal Chemical Co., Inc.

41341202 McManus, J. (1989) PCNB: Nature of the Residue in Peanuts (Progress Report): Lab Project Number: 8758. Unpublished study prepared by Uniroyal Chemical Co., Inc.

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References (not used)

[The following references duplicate previously cited information, were reviewed for the Guidance Document, or are irrelevant to this update.]

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00165373 Olin Corp. (1983) Residues of PCNB in Beans and Peanuts. Unpublished compilation. 265 p.

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00165639 Thomas, M. (1965) Letter sent to H. Klein dated Oct 27, 1965: Residue analyses of samples from 1965 Terraclor Super X field tests on peanuts. Prepared by Olin Corp. 3 p.

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40866004 Malek, D. (1977) Letter sent to T. Evrard dated Dec 8, 1977: Pinto beans: [Terraclor and allied metabolites in ..]. 2 p.

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40866006 Kuchar, E. (1974) Letter sent to L. Faulkner dated Dec 2, 1974: Terraclor residues--Pinto Harvest Beans 1974 crop. 4 p.

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40866008 Kuchar, E. (1972) Letter sent to H. Klein dated Nov 9, 1972: Terraclor residues in cabbage. 3 p.

40866010 DeFelice, D. (1977) Letter sent to E. Kuchar dated Oct 7, 1977: Cabbage samples--1977: [Terraclor, impurities and metabolites]. 2 p.

40866011 Kuchar, E. (1970) Letter sent to H. Klein dated Oct 14, 1970: Terraclor experiments--peanut related material. 6 p.

40866012 Baxter, M. (1978) Letter sent to T. Evrard dated May 05, 1978: Peanut and soil samples--HCS free terraclor. 4 p.

40866013 Heikes, D. (1980) Residue of pentachloronitrobenzene and related compounds in peanut butter. Bull. Environm. Contam. Toxicol. 24: 338-343.

40866014 Burger, R. (1979) Letter sent to T. Evrard dated Mar 2, 1979: Potatoes treated with terrazole and terraclor. 6 p.

40866015 Malek, D. (1978) Letter sent to T. Evrard dated Jan 12, 1978: Potato and soil samples: [Terraclor, impurities and metabolites]. 5 p.

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40866208 Dejonckheere, W.; Steurbaut, W.; Kips, R. (1975) The fate of quintozene (PCNB) on lettuce. Mededelingen van de Faculteit Landbou wwetenschappen Rijksuniversiteit Gent 40(2,Pt.2):1033-1038.

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TABLE A. GENERIC DATA REQUIREMENTS FOR PCNB.

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]		Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.240 Residue Chemistry					
171-2. Chemical Identity[3]					
171-3. Directions for Use		(See Index)[4,5]			
171-4. Nature of the Residue (Metabolism) - Plants	PAIRA	Partially	41341201 41341203	41341202	Yes[6]
171-4. Nature of the Residue (Metabolism) - Livestock	PAIRA & plant metabolites	Partially	41303101 41341204	41303301 41341205	Yes[7]
171-4. Residue Analytical Methods	TGAI & metabolites	Partially			Yes[8]
171-4. Storage Stability	TEP & metabolites	Partially	40921600	40921601	Yes[9]
171-4. Magnitude of Residue in Plants					
Root and Tuber Vegetables - Potatoes	TEP	Partially	40816701		Yes[10]
(processed commodities)	TEP	Partially	40070401 40457401	40088401	Yes[11]

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Bulb Vegetables				
- Garlic	TEP	Partially		Yes[12]
Leafy Vegetables (except Brassica)				
- Lettuce	TEP	No		Yes[13]
Brassica Leafy Vegetables				
- Broccoli	TEP	Partially	40816702	Yes[14]
- Brussels sprouts	TEP	Partially		Yes[15]
- Cabbage	TEP	Partially	40816703	Yes[16]
- Cauliflower	TEP	Partially		Yes[17]
- Collards, Kale, and Mustard greens	TEP	Yes	00158795	No
Legume Vegetables				
- Beans (succulent & dried)	TEP	Partially	40816704	Yes[18]
(processed commodities)	TEP	No		Yes[19]
Fruiting Vegetables (Except Cucurbits)				
- Peppers	TEP	Partially	40816705	Yes[20]
- Tomatoes	TEP	Partially		Yes[21]
(processed commodities)	TEP	No		Yes[22]

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Small Fruits & Berries				
- Strawberries	TEP	No		Yes[13]
Non-grass Animal Feeds				
- Alfalfa forage & hay	TEP	No		Yes[13]
- Clover forage & hay	TEP	No		Yes[13]
Miscellaneous Commodities				
- Bananas	TEP	Partially		Yes[23]
- Cottonseed	TEP	Partially	41341206	Yes[24]
(processed commodities)	TEP	Partially	41341206	Yes[25]
- Peanuts	TEP	Partially	41002507	Yes[26]
(processed commodities)	TEP	Partially		Yes[27]
- Seed Treatment	TEP	Partially	40862901	Yes[28,29,30,31 32,33]
171-4. Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially		Reserved[34]
171-4. Magnitude of residue - Potable Water	TEP	No		Reserved[35]
- Fish	TEP	No		Reserved[35]
- Irrigated Crops	TEP	No		Reserved[35]

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
- Food Handling	TEP	No		Reserved[35]

1. Test substance: PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = Typical end-use product; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

2. These references were submitted in response to the PCNB Guidance Document dated 1/87. Underlining indicates documents that have been reviewed in this update.

3. The same chemical identity data are required as under 40 CFR §158.150-190, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

4. The 3/89 update of the index of uses for PCNB was used to create this document.

5. The Guidance Document required numerous label amendments and clarifications. The following requirements remain outstanding: The registrant must amend all pertinent product labels to specify a maximum single application rate (expressed in lb ai/A) and a maximum seasonal rate or number of applications per season; a minimum interval between applications and a PHI must also be specified. The requested data must reflect these specifications.

6. The registrant has submitted progress reports for the required plant metabolism studies. The following data requirements remain outstanding: Data depicting the uptake, distribution, and metabolism of ring-labeled [^{14}C]PCNB in three dissimilar crops (peanuts, potatoes, and cabbage). A completely characterized test substance representative of technical PCNB used in commercial formulations (including impurities) must be applied under conditions representing normal cropping practices and at rates high enough to permit characterization of ^{14}C-residues. The identities and quantities of residues in mature plant parts must be determined in order to elucidate terminal residues. Confirmation of the identities of residues using a

TABLE A. (Continued).

suitable method such as mass spectrometry (MS) or high performance liquid chromatography (HPLC) is also required. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to ascertain that the methods are capable of adequately recovering and quantifying all metabolites of concern.

7. Data depicting the metabolism of ring-labeled [^{14}C]PCNB in ruminants and poultry. For the poultry study in progress (MRID 41341204), the dietary feeding level, and conditions under which tissue hydrolysis were conducted must be reported. The distribution and identities of residues must be determined in eggs, muscle, liver, fat, and skin. For the submitted study on goats, the registrant must explain the discrepancies in the two submissions and present evidence that the data in MRID 41341205 reflect analysis of tissues from the same animal described in MRID 41303301. In addition, the registrant must report the fraction of the TRR partitioned into each solvent used in the extraction and into bound residue for milk, fat, and liver (and muscle, if warranted by the TRR in muscle), and for each extract that was analyzed by HPLC, the registrant must provide the amount of radioactivity applied in each HPLC analysis and the amount of radioactivity detected in the identified radioactive zones. Data depicting the nature of the residues in swine may also be required if studies with ruminants reveal that the metabolism of PCNB in these animals differs from that in rats. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to ascertain that the methods are capable of adequately recovering and quantifying all metabolites of concern.

8. Data are required depicting the recovery of PCA, MPCPS, PCB, and HCB using FDA Multiresidue Protocols C and D, published in Pesticide Analytical Manual (PAM) Vol. I and available from the National Technical Information Service (NTIS) under order No. PB 203734/AS. The nature of the residue in plants and animals is not adequately understood. If the metabolism studies requested in the sections "Qualitative Nature of the Residue in Plants" and "Qualitative Nature of the Residue in Animals" reveal the presence of additional metabolites of concern, additional validated methods for data collection and tolerance enforcement will be required.

9. The storage stability data submitted in response to the Guidance Document do not fulfill the requirements for this topic because: No data were submitted on the intervals and conditions of residue sample storage called for in the Guidance Document, nor were there any data on the storage stability of residues in animal commodities. Since the data failed to show any pattern of residue decline in related crops, additional data on all pertinent commodities are required. For crops for which no storage stability data are available, additional decline data are required unless samples are analyzed within 2 weeks of harvest. The following additional data are required: The sample storage conditions and intervals must be

TABLE A. (Continued).

supplied for all required and previously submitted residue data for plant and animal commodities. Storage stability data on PCNB and residues of concern in support of previously submitted residue data are required for only those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of PCNB residues of concern in commodities stored under the range of conditions and for the range in intervals specified. Crop samples bearing measurable weathered residues or fortified with PCNB residues of concern and fortified meat and milk samples must be analyzed immediately after harvest or fortification and again after storage intervals that allow for reasonable unforseen delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field weathered samples are used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the registrant is referred to an August, 1987 Position Document on the Effects of Storage Validity of Pesticide Residue Data available from NTIS under order no. PB 88112362/AS. The nature of the residue in plants and animals is not adequately understood. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting stability of these residues during storage will be required.

10. Data reflecting broadcast and in-furrow applications of an EC formulation are currently under review by the Agency. Additional data submitted regarding potatoes are not useful for assessing the established or proposed tolerance because information concerning the location and methods of field application and analytical methodology were not provided. The following additional data requirements remain outstanding: Data depicting PCNB residues of concern in or on potatoes following preplant broadcast application using a representative G, EC, and WP formulation at 25 lb ai/A and an in-furrow at planting application using these same formulations each at 10 lb ai/A. The tests must be conducted in ID(26%), OR(7%) or WA(17%), CA(5%), MI(3%) or WI(6%), MN(5%) or ND(6%), ME(6%), and FL(2%), since these states represent the major U.S. potato-growing regions accounting for ca. 80% of U.S. production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

11. The registrant has stated the intent to submit the required processing data. Until the data have been reviewed and judged adequate, the following requirements remain outstanding: Data depicting the potential for residue concentration of PCNB residues of concern in wet and dry peel processed from potatoes treated at at least 5x the maximum registered rate bearing measurable weathered residues. The formulation(s) used must represent technical PCNB containing <0.1% HCB. Samples must be analyzed using the methodology described in MRID 40457401, validated at 0.001 ppm for HCB. If residues concentrate in either commodity, an appropriate feed additive tolerance will be required.

TABLE A. (Continued).

12. The PCNB Guidance Document dated 1/87 requires the product labeling for in-furrow treatment be amended to specify the spray band width as well as the number of row-feet per field acre. The updated EPA Index to Pesticide Chemicals dated 3/89 lists no such specifications. The following requirement remains outstanding: All product labels bearing directions for in-furrow application to garlic must be amended to specify both the spray band width and the number of row-feet per acre.

13. Tolerances must be proposed for PCNB residues of concern in or on lettuce, strawberries, alfalfa forage, alfalfa hay, clover forage, and clover hay, and submit appropriate supporting residue data. Alternatively, the registrant may elect to cancel these uses permitted under AZ State Reg. No. N, CA State Reg. Nos. 10972-50043 AA and 10972-50199 AA, and TX State Reg. No. 74.

14. The broccoli data submitted in response to the Guidance Document are currently under review by the Agency. Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding: Data depicting PCNB residues of concern in or on broccoli resulting from pre-transplanting broadcast incorporated soil application of the 10% G and 75% WP formulations at 60 lb ai/A followed by at-transplanting application at 40 lb ai/A (13,000 row-feet) incorporated into a 14-inch band. Data are also required reflecting at-transplant application at 60 lb ai/A in a transplant solution. Tests must be conducted in CA (90%) and TX(5%) since these states accounted for ca. 95% of the 1986 U.S. broccoli production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87).

15. The PCNB Guidance Document dated 1/87 concludes that the data required for broccoli will, by translation, satisfy the requirement for data on Brussels sprouts.

16. The cabbage data submitted in response to the Guidance Document are currently under review by the Agency. Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding: Data depicting PCNB residues of concern in or on cabbage resulting from pre-transplanting broadcast incorporated soil application of the 10% G and 75% WP formulations at 60 lb ai/A followed by at-transplanting application at 40 lb ai/A (13,000 row-feet) incorporated into a 14-inch band. Data are also required reflecting at-transplant application at 60 lb ai/A in a transplant solution. Tests must be conducted in CA(8%), FL(16%), NY(15%), NC(5%), TX(16%), and WI(9%) since these states accounted for ca. 70% of the 1986 U.S. cabbage production (1982 Census of Agriculture, Vol. I, Part 51, p. 338).

TABLE A. (Continued).

17. The PCNB Guidance Document dated 1/87 concludes that the data required for broccoli will, by translation, satisfy the requirement for data on cauliflower.

18. The data on beans submitted in response to the Guidance Document are currently under review by the Agency. Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding: Data depicting PCNB residues of concern in or on snap, lima, and dry beans and bean vines and hay following four applications of the 75% WP and 2 lb/gal EC formulations; the first application should be made at 1.5 lb ai/A and the subsequent applications must be made at 14-day intervals at 2 lb ai/A. The tests on dry beans must be conducted in CA(12%), CO(10%), ID(11%), MI(21%), NE(13%), and ND(19%); tests on snap beans must be conducted in NY(10%), OR(23%, and WI(41%); and tests on lima beans must be conducted in CA. [Production data in parentheses were obtained from Agricultural Statistics Board, NASS, USDA; 1986 Vegetables Summary.] Based on the residue data, tolerances must be established for PCNB residues of concern in or on bean vines and hay; alternatively, the registrant may propose to add amend the pertinent product labels to include a feeding restriction.

19. The processing data submitted in response to the Guidance Document are currently under review by the Agency. Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding: Data depicting the potential for concentration of PCNB residues of concern in cannery waste processed from beans bearing measurable weathered residues. If residues concentrate in this commodity, an appropriate feed additive tolerance must be proposed. A tolerance for residues in or on bean vines and hay supported by adequate residue data may substitute for the requirement for a processing study on cannery waste.

20. The data submitted in response to the Guidance Document are currently under review by the Agency. Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding: Data depicting PCNB residues of concern in or on peppers resulting from in-furrow transplant applications of the 75% WP formulation at 7.5 lb ai/A and in a transplant solution at 34 lb ai/A. Tests must be conducted in CA(18%), FL(23%), NC(10%), and TX(16%), since these states accounted for ca. 70% of the 1986 U.S. sweet pepper production (1982 Census of Agriculture, Vol. I, Part 51, p. 350).

21. The available data do not fulfill the requirements for this topic because the submitted volume contained no residue or processing data. Until it has been determined that sufficient data are available for tolerance assessment, the following requirements remain outstanding: Data depicting PCNB residues of concern in or on tomatoes resulting from in-furrow transplant applications of the 75% WP formulation at 7.5 lb ai/A and in a transplant solution at 25.5 lb ai/A. Tests must be conducted in CA(77%), FL(9%), and

TABLE A. (Continued).

IN(2%), MI(2%), or OH(5%), since these states accounted for ca. 95% of the 1986 U.S. tomato production (Agricultural Statistics Board, NASS, USDA, 1987, Vegetables, 1986 Summary, pp. 16 and 53).

22. The following requirements remain outstanding: Data depicting the potential for concentration of PCNB residues of concern in juice, puree, catsup, and dry pomace processed from tomatoes bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food or feed additive tolerance must be proposed.

23. No data were submitted in response to the Guidance Document. The following additional data are required: Data depicting PCNB residues of concern in or on bananas treated using the 1.63% RTU formulation at 1 gallon of product/700-800 stems. The stems should be dipped at the butt and tip end and the remainder of the dose brushed onto cuts and scrapes along the stems. Whole bananas must be sampled immediately after treatment and again after arrival at the U.S. port of entry following intercontinental shipment under representative transport conditions; the data must reflect minimum and maximum anticipated shipment intervals. In addition, copies of the labels for all PCNB products currently used in countries that export bananas to the U.S. must be submitted.

24. The data submitted in response to the Guidance document do not reflect application of a G formulation at 1x or application using a WP formulation. Data are required depicting PCNB residues of concern in or on cottonseed resulting from in-furrow and surface band over-the row applications made at-planting using a representative G formulation at 5 lb ai/A and a WP formulation at 2 lb ai/A. Tests must be conducted in AZ(7%), CA(20%), LA(7%), MS(12%), and TX(32%), since these states accounted for ca. 80% of the 1987 U.S. cotton production (Agricultural Statistics Board, NASS, USDA, Crop Database, Jan, 1988).

25. The submitted data are insufficient. In order to adequately assess the potential for concentration of residues during processing, additional data are needed reflecting detectable residues resulting from treatment at an exaggerated rate >2x. Data are required depicting PCNB residues of concern in or on cottonseed resulting from in-furrow and surface band over-the row applications made at-planting using a representative G formulation at 5 lb ai/A and a WP formulation at 2 lb ai/A. Tests must be conducted in AZ(7%), CA(20%), LA(7%), MS(12%), and TX(32%), since these states accounted for ca. 80% of the 1987 U.S. cotton production (Agricultural Statistics Board, NASS, USDA, Crop Database, Jan, 1988).

26. The peanut data submitted in response to the Guidance Document do not fulfill the requirements for this topic because no acceptable data were submitted reflecting soil applications, aerial applications, or overhead sprinkler applications in OK or TX. Additional data from field trials on peanuts are not useful

TABLE A. (Continued).

for tolerance assessment because application was made >150 days before harvest, the formulation used was not specified, and the method of application was not reported. The following additional data are required: Data depicting PCNB residues of concern in or on peanut nutmeats and hulls harvested 45 days following surface-banded application made at pegging using the 30% G and 75% WP formulations each at 10 lb ai/A in separate tests. Tests must be conducted in AL(13%) or GA(44%), NC(11%) or VA(6%), and OK(6%) or TX(12%), since these states accounted for ca. 80% of the 1987 U.S. peanut production (Agricultural Statistics Board, NASS, USDA, Crop Database, Jan, 1988).

Data are also required depicting PCNB residues of concern in or on peanut nutmeats and hulls harvested 45 days following overhead sprinkler application of the 75% WP and 2 lb/gal EC formulations at 10 lb ai/A, made at pegging. The tests must be conducted in TX to represent the states where this use is permitted. Alternatively, the registrant may elect to cancel these uses permitted under EPA SLN Nos. OK840008, TX790017, and TX840015.

Data are required depicting PCNB residues of concern in or on peanut nutmeats and hulls harvested 45 days following aerial application of the 10% G formulation at 10 lb ai/A made at pegging. The test must be conducted in TX where this use is permitted. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. TX780043.

27. The processing data submitted do not fulfill the requirements for this topic because spiked samples were used and no commodities of interest were analyzed. The following additional data are required: Data depicting the potential for concentration of PCNB residues of concern in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food or feed additive tolerance must be proposed. If the requested plant metabolism data reveal residues of concern other than PCNB, PCA, MPCPS, PCB, and HCB, additional processing data on meal and crude oil will be required.

28. In response to the Guidance Document, data were submitted indicating that commodities of corn, peas, sugar beets, soybeans, and wheat grown from treated seed bore detectable residues. The Agency has determined that seed treatments using PCNB should not be categorized as non-food uses and that tolerances must be proposed for PCNB residues of concern in or on commodities of these crops. It was noted that, after the nature of the residue in plants is adequately elucidated, field trials should be conducted to support the proposed tolerances.

TABLE A. (Continued).

29. The registrant must propose tolerances for PCNB residues of concern in or on corn grain, forage, and fodder grown from seed treated using a representative D and an EC or RTU formulation at 0.046 lb ai/100 lb of seed. In one test for each formulation, seed should be treated at 1.29 lb ai/100 lb of seed (28x); if no detectable residues result in grain, a processing study will not be required. The tests must be conducted in CO(2%), GA(1%), IL(17%), IA(18%), NE(11%) and TX(2%), since these states accounted for ca. 50% of 1987 U.S. corn grain production and represent the major U.S. corn-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

30. The registrant must propose tolerances for PCNB residues of concern in or on soybean seed, forage, and hay grown from seed treated using a representative D and an EC or RTU formulation at 0.105 lb ai/100 lb of seed. In one test for each formulation, seed should be treated at 0.57 lb ai/100 lb of seed (5.4x); if no detectable residues result in soybeans, a processing study will not be required. The tests must be conducted in IA(18%), LA(2%), MN(10%), MO(8%), OH(8%), and TN(2%), since these states accounted for ca. 50% of 1987 U.S. soybean production and represent the major U.S. soybean-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

31. The registrant must propose tolerances for PCNB residues of concern in or on peas (succulent and dried), vines, and hay grown from seed treated using a representative D and an EC or RTU formulation at 0.105 lb ai/100 lb of seed. The tests must be conducted in DE(succulent, 4%), ID(dry, 37%), MI(succulent, 23%), NY(succulent, 4%), WA(dry, 63%; succulent, 20%), and WI(28%), since these states accounted for virtually all of the 1987 U.S. production of succulent and dry peas (Agricultural Statistics Board, NASS, USDA, 1987-1988; Crops Database, 1/88, and Vegetables, 1986 Summary).

32. The registrant must propose tolerances for PCNB residues of concern in or on sugar beet roots and tops grown from seed treated using representative D, EC, and FlC formulations at 0.25 lb ai/100 lb of seed. The tests must be conducted in CA(22%), CO(3%), ID(15%), MI(10%), MN(22%), and OR(2%), since these states accounted for ca. 70% of 1987 U.S. sugar beet production and represent the major U.S. sugar beet-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

33. The registrant must propose tolerances for PCNB residues of concern in or on wheat grain, forage, hay, and straw grown from seed treated using a representative D formulation at 0.062 lb ai/bu and a representative EC or RTU formulation at 0.053 lb ai/100 lb of seed. The tests must be conducted in CA(2%), CO(5%), KS(17%), OK(6%), TX(5%), and WA(5%), since these states accounted for ca. 40% of 1987 U.S. wheat production and represent the major U.S. wheat-growing regions (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

TABLE A. (Continued).

34. The nature of the residue in animals is not understood. On receipt of the requested animal metabolism data, the need for and nature of tolerances for residues of PCNB in meat, milk, poultry, and eggs will be determined.

35. These requirements are reserved until such time as data indicate that the magnitude of the residue at these sites pose concerns.