

US EPA ARCHIVE DOCUMENT



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

JAN 31 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Lindane Product and Residue Chemistry Reregistration
Standard Updates and CBRS # 6961.

FROM: E. Zager, Acting Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

A handwritten signature in dark ink, appearing to read "Edward Zager".

TO: Lois Rossi, Chief
Reregistration Branch
Special Review & Reregistration Division (H7508C)

and

Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Attached are the updates to the Product and Residue Chemistry Chapters of the Lindane Reregistration Standard. These updates were prepared by Dynamac Corporation under supervision of CBRS, HED. They have undergone secondary review in the branch and have been revised to reflect Agency policies.

Revised data requirement tables are included.

If you need additional input please advise.

Attachment 1: Lindane Product Chemistry Reregistration Standard Update.

Attachment 2: Lindane Residue Chemistry Reregistration Standard Update.

cc (With Attachments 1 and 2): RBP, Lindane Reregistration Standard file, Lindane Subject File, C. Furlow (PIB/FOD), J. Burrell (FOD), Dynamac.

cc (With Attachment 2) : Circulation (7).

cc (Without Attachments): RF, P. Fenner-Crisp (HED).

Final Report

LINDANE
Task 4: Product Chemistry
Registration Standard Update

January 18, 1991

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

LINDANE

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

INTRODUCTION

A Product Search Listing conducted 7/30/90 identifies several manufacturing-use products (MPs) containing lindane; these products are listed below in Table 1. Technical (T) lindane is not manufactured in the United States. All of the technical lindane used in this country is imported and repackaged.

Table 1. Lindane manufacturing-use products.

Product	EPA Reg. No.	Registrant
99.5% T ^a	264-454	Rhone-Poulenc Ag Company, Inc.
99.5% T ^a	264-455	
99.5% T ^a	21137-3	EM Industries, Inc.
99.5% T	40083-1	Inquinosa (Industrias Quimicas del Noroeste S.A.)
99.5% T ^b	655-28	Prentiss Drug & Chemical Co., Inc.
99.5% T ^b	655-393	
99.5% T	5481-225	Amvac Chemical Corp.
99% T	11220-19	Trical
99.5% T	19713-61	Drexel Chemical Company
99.5% T ^a	19713-191	
100% T ^c	63823-12	Management Contract Services, Inc.
99.5% T ^{a,d}	63823-13	

^a Listed on the Product Search Listing as a formulation intermediate (FI); however, based on manufacturing process and product composition, this is a technical product (T), and will be referred to as such throughout this document.

^b Listed on the Product Search Listing as a 99% formulation; however, label changes to 99.5% were accepted 11/25/88.

^c Transferred from Wesley Industries (EPA Reg. No. 47916-45) on 6/2/90.

^d Transferred from Wesley Industries (EPA Reg. No. 47916-46) on 6/2/90. Listed on the Product Search Listing as a 99% formulation; however, label changes to 99.5% were accepted 1/18/89.

The Lindane Guidance Document dated 9/85 requires additional generic and product-specific product chemistry data for lindane manufacturing-use products. In response to the Guidance Document requirements, members of The Centre International d'Etudes du Lindane, CIEL, (Rhone-Poulenc, Inc., EM Industries, Inc. representing Celamerck GmbH & Co., and Inquinoso) have submitted data developed jointly. The following registrants have entered into joint data agreements with CIEL in accordance with the provisions of FIFRA §3(C)(2)(B)(ii): Prentiss, Amvac, and Management Contract Services. Data submitted in response to the Guidance Document by CIEL members Rhone-Poulenc and Inquinoso (1986; MRIDs 00160127, 00160128, 00160129, 00160130, 00164782, and 00164783), and by Drexel (1986; MRID 00164198) are reviewed in this Update document for their adequacy in fulfilling outstanding data requirements.

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 lindane.

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:

- For the Rhone-Poulenc 99.5% Ts (EPA Reg. Nos. 264-454 and 264-455) additional data must be submitted pertaining to product composition, starting materials and manufacturing process, preliminary analysis, certified limits, oxidizing/reducing action, explodability, storage stability, and corrosiveness.
- For the EM Industries, Inc. 99.5% T (EPA Reg. No. 21137-3) additional data must be submitted pertaining to product composition, starting materials and manufacturing process, preliminary analysis, certified limits,

oxidizing/reducing action, explodability, storage stability, and corrosiveness.

- For the Inquinoso 99.5% T (EPA Reg. No. 40083-1) additional data must be submitted pertaining to product composition, starting materials and manufacturing process, preliminary analysis, certified limits, oxidizing/reducing action, explodability, storage stability, and corrosiveness.
- For the Prentiss Drug and Chemical Co. 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393) additional data must be submitted pertaining to starting materials and manufacturing process, preliminary analysis, oxidizing/reducing action, explodability, storage stability, and corrosiveness.
- For the Amvac Chemical Corp. 99.5% T (EPA Reg. No. 5481-225) additional data must be submitted pertaining to product composition, starting materials and manufacturing process, preliminary analysis, certified limits, oxidizing/reducing action, explodability, storage stability, and corrosiveness.
- For the Trical 99% T (EPA Reg. No. 5481-225) data must be submitted pertaining to product composition, starting materials and manufacturing process, discussion of the formation of impurities, preliminary analysis, certified limits, enforcement analytical methods, octanol/water partition coefficient, oxidizing/reducing action, explodability, storage stability, and corrosiveness.
- For the Drexel 99.5% Ts (EPA Reg. Nos. 19713-61 and 19713-191) additional data must be submitted pertaining to product composition, starting materials and manufacturing process, discussion of the formation of impurities, preliminary analysis, certified limits, enforcement analytical methods, octanol/water partition coefficient, oxidizing/reducing action, explodability, storage stability, and corrosiveness.
- For the Management Contract Services, Inc. 100% and 99.5% Ts (EPA Reg. Nos. 63823-12 and 63823-13, respectively) data must be submitted pertaining to product composition, starting materials and manufacturing process, preliminary analysis, certified limits, oxidizing/reducing action, explodability, storage stability, and corrosiveness.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Composition

The Lindane Guidance Document dated 9/85 does not require additional generic or product-specific data concerning product composition. However, updated Confidential Statements of Formula (CSFs) have been submitted for several products; these are presented in Confidential Appendix A and conclusions are cited below.

EM Industries submitted a CSF dated 3/17/86 (product registration jacket) which does not satisfy the requirements of 40 CFR §158.155 (Guidelines Reference No. 61-1) regarding product identity for the EM Industries 99.5% T (EPA Reg. No. 21137-3) because the identity, purpose, and nominal concentration must be submitted for each inert ingredient present at ≥0.1%. Additional data are required.

Prentiss Drug & Chemical Co. submitted CSFs dated 12/14/87 (product registration jackets) which satisfy the requirements of 40 CFR §158.155 (Guidelines Reference No. 61-1) regarding product identity for the 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393). No additional data are required. However, the nominal concentrations (99.0) do not agree with the revised label claims (99.5%); updated CSFs reflecting the revised nominal concentrations must be submitted.

Confidential Statements of Formula submitted by Amvac (dated 6/19/86; product registration jacket) for the 99.5% T (EPA Reg. No. 5481-225) and Management Contract Services (dated 5/3/88; product registration jacket) for the 100% T and 99.5% T (EPA Reg. Nos. 63823-12 and 63823-13) do not satisfy the requirements of 40 CFR §158.155 (Guidelines Reference No. 61-1) regarding product identity because the nominal concentration of the active ingredient must be based on the nominal concentration of the active ingredient in the technical source product. In addition, the label claim for the Management Contract Services 100% T (EPA Reg. No. 63823-12) should be changed. Additional data are required.

Current CSFs were not available for review for the following products: the Rhone Poulenc 99.5% Ts (EPA Reg. Nos. 264-454 and 264-455), the Inquinoso 99.5% T (EPA Reg. No. 40083-1), the Trical 99% T (EPA Reg. No. 11220-19), and the Drexel 99.5% Ts (EPA Reg. Nos. 19713-61 and 19713-191). Updated CSFs are required for proper evaluation of product chemistry data for each product. Additional data are required pertaining to product identity for these products.

61-2. Starting Materials and Manufacturing Process

The Lindane Guidance Document dated 9/85 specifies generic and product-specific data requirements for lindane regarding starting materials and the manufacturing processes. Data submitted in response to the Guidance Document are presented in Confidential Appendix B; conclusions are discussed below.

CIEL members, Rhone-Poulenc (1986; MRID 00160128) and Inquinosa (1986; MRID 00160127), submitted identical descriptions of the starting materials and manufacturing process for their 99.5% Ts (EPA Reg. Nos. 264-454, 264-455, and 40083-1). These data do not satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the manufacturing process because the following information was not provided: (i) amounts and order in which the starting materials were added; (ii) clarification of whether the process is a batch or continuous process; (iii) duration of each step and the total process; (iv) description of the equipment used in the process; and (v) quality control measures used to ensure the integrity of the product. Additional information is required.

Once the outstanding data requirements have been met, this information will satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) for the Rhone-Poulenc 99.5% T's (EPA Reg. Nos. 264-454 and 264-455), the EM Industries 99.5% T (EPA Reg. No. 21137-3), the Inquinosa 99.5% T (EPA Reg. No. 40083-1), the Prentiss 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393), the Amvac 99.5% T (EPA Reg. No. 5481-225), and the Management Contract Services 100% T and 99.5% T (EPA Reg. Nos. 63823-12 and 63823-13).

Drexel (1986; MRID 00164198) submitted a description of the starting materials and manufacturing process for the 99.5% T (EPA Reg. No. 19713-191). This information does not satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the manufacturing process for the Drexel 99.5% T (EPA Reg. No. 19713-191) because the following information was not provided: (i) technical specifications and suppliers for all starting materials; (ii) amounts and order in which the starting materials were added; (iii) clarification of whether the process is a batch or continuous process; (iv) duration and controlled parameters (temperature, humidity, and pressure) of each step and the total process; (v) description of the equipment used in the process; and (vi) quality control measures used to ensure the integrity of the product. Additional information is required.

No information pertaining to the starting materials and formulation/manufacturing processes has been submitted for the Trical 99% T (EPA Reg. No. 11220-19) and the Drexel 99.5% T (EPA

Reg. No. 19713-61). Data requirements remain outstanding for these products.

61-3. Discussion of the Formation of Impurities

The Lindane Guidance Document dated 9/85 requires generic and product-specific data for lindane regarding discussion of formation of impurities, with specific reference to the potential for formation of dioxins and dibenzofurans.

In response to the Guidance Document, CIEL member Rhone-Poulenc (1986; MRID 00160129) submitted a discussion of the formation of impurities during the manufacture of technical lindane, including a discussion of the potential for formation of dioxins and dibenzofurans, for the 99.5% Ts (EPA Reg. Nos. 264-454 and 264-455). These discussions are presented in Confidential Appendix C. This information satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the Rhone-Poulenc 99.5% T's (EPA Reg. Nos. 264-454 and 264-455), the EM Industries 99.5% T (EPA Reg. No. 21137-3), the Inquinosa 99.5% T (EPA Reg. No. 40083-1), the Prentiss 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393), the Amvac 99.5% T (EPA Reg. No. 5481-225), and the Management Contract Services 100% T and 99.5% T (EPA Reg. Nos. 63823-12 and 63823-13). No additional information is required.

No information pertaining to discussion of formation of impurities was submitted for the Trical 99% T (EPA Reg. No. 11220-19) and the Drexel 99.5% Ts (EPA Reg. Nos. 19713-61 and 19713-191). Data requirements remain outstanding for these products.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Lindane Guidance Document dated 9/85 specifies generic and product-specific data requirements for lindane regarding preliminary analysis. Data submitted by the registrants in response to the Guidance Document are presented in Confidential Appendix D and the conclusions are discussed below.

CIEL members Rhone-Poulenc (1986; MRID 00164782) and Inquinosa (1986; MRID 00164783) submitted preliminary analysis data for their 99.5% T's (EPA Reg. Nos. 264-454, 264-455, and 40083-1), including analysis for dioxins and dibenzofurans at the 1 ppb level, which do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis because the registrants did not establish that the method used for analysis of dioxins and dibenzofurans could quantitate the

reference standard, 2,3,7,8-TCDD, to 0.1 ppb. Additional data are required.

Once outstanding data requirements have been met, these data will satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) for the Rhone-Poulenc 99.5% T's (EPA Reg. Nos. 264-454 and 264-455), the EM Industries 99.5% T (EPA Reg. No. 21137-3), the Inquinoso 99.5% T (EPA Reg. No. 40083-1), the Prentiss 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393), the Amvac 99.5% T (EPA Reg. No. 5481-225), and the Management Contract Services 100% T and 99.5% T (EPA Reg. Nos. 63823-12 and 63823-13)

Drexel submitted data (1986; MRID 00164198) which do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the Drexel 99.5% T (EPA Reg. No. 19713-191) because the preliminary analysis did not include all components present at ≥0.1% and did not include analysis for dioxins or dibenzofurans. Additional data are required.

No data pertaining to preliminary analysis were submitted for the Trical 99% T (EPA Reg. No. 11220-19) and the Drexel 99.5% T (EPA Reg. No. 19713-61). Data requirements remain outstanding for these products.

62-2. Certified Limits

The Lindane Guidance Document dated 9/85 specifies generic and product-specific data requirements for lindane regarding certification of ingredient limits. Data submitted by the registrants in response to the Guidance Document are presented in Confidential Appendix A and conclusions are discussed below.

CIEL member Rhone-Poulenc submitted a statement of proposed certified limits (1986; MRID 00164782) for the 99.5% Ts (EPA Reg. Nos. 264-454 and 264-455) which does not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits because an upper certified limit was not submitted for the active ingredient. The registrant must submit these certifications on EPA Form 8570-4 (Rev. 2-85). Additional data are required.

Prentiss Drug & Chemical Co. submitted CSFs for the 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393) which satisfy the requirements of 40 CFR §158.175 (Guidelines Reference No. 62-2) regarding certified limits for the Prentiss 99.5% Ts (EPA Reg. No. 655-28 and 655-393). No additional data are required.

Amvac submitted a CSF for the 99.5% T (EPA Reg. No. 5481-225) which does not satisfy the requirements of 40 CFR §158.175 (Guidelines Reference No. 62-2) regarding certified limits

because the registrant referenced certified limits for the active ingredient in the technical source product, instead of proposing specific certified limits for the active ingredient in the 99.5% T (EPA Reg. No. 5481-225). The registrant must submit updated certified limits on EPA Form 8570-4 (Rev. 2-85). Additional data are required.

Drexel submitted a certification of limits statement (1986; MRID 00164198) which satisfies the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the 99.5% T (EPA Reg. No. 19713-191). No additional data are required for this topic; however, certified limits must be submitted on EPA Form 8570-4 (Rev. 2-85).

Management Contract Services submitted CSFs for the 100% T and 99.5% T (EPA Reg. Nos. 63823-12 and 63823-13) which do not satisfy the requirements of 40 CFR §158.175 regarding certified limits because certified limits for the active ingredient were based on the amount of technical source product used rather than on the nominal concentration of active ingredient in the source technical product. The registrant must submit updated certified limits on EPA form 8570-4 (Rev. 2-85). The forms must reflect the new registrant and registration numbers. In addition, the registrant is required to certify that the manufacturing process and location have not changed since transfer of the products from Wesley Industries. Additional data are required.

Information pertaining to certified limits is either unavailable for review or has not been submitted for the EM Industries 99.5% T (EPA Reg. No. 21137-3), the Inquinoso 99.5% T (EPA Reg. No. 40083-1), the Trical 99% T (EPA Reg. No. 11220-19), and the Drexel 99.5% T (EPA Reg. No. 19713-61). Data requirements remain outstanding for these products.

62-3. Enforcement Analytical Methods

The Lindane Guidance Document dated 9/85 specifies generic and product-specific data requirements for lindane regarding analytical methods to verify certified limits.

CIEL member Rhone-Poulenc (1986; MRID 00164782) submitted enforcement analytical methods for the determination of lindane per se and its impurities. The analytical methods for the determination of impurities are discussed in Confidential Appendix E.



[REDACTED]

If the registrant intends to select the CIPAC method for enforcement of certified limits, then a complete description of the method is required along with complete validation data.

These data satisfy the requirements of 40 CFR §158.180 (Guideline Reference No 62-3) regarding enforcement analytical methods for the Rhone-Poulenc 99.5% T's (EPA Reg. Nos. 264-454 and 264-455), the EM Industries 99.5% T (EPA Reg. No. 21137-3), the Inquinoso 99.5% T (EPA Reg. No. 40083-1), the Prentiss 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393), the Amvac 99.5% T (EPA Reg. No. 5481-225), and the Management Contract Services 100% T and 99.5% T (EPA Reg. Nos. 63823-12 and 63823-13). No additional data are required.

Drexel (1986; MRID 00164198) submitted a GC method for analysis of lindane in the technical product.

[REDACTED]

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No 62-3) regarding enforcement analytical methods for the Drexel 99.5% Ts (EPA Reg. Nos. 19713-61 and 19713-191) because no validation data or statements regarding precision and accuracy were provided for the methods. Furthermore, because additional data are required for this product pertaining to discussion of the formation of impurities and preliminary analysis, additional impurities of toxicological significance may yet be identified. In addition, no enforcement analytical methods have been submitted for additional ingredients or impurities that may be determined to be toxicologically significant. Additional data are required.

No information pertaining to enforcement analytical methods has been submitted for the Trical 99% T (EPA Reg. No. 11220-19). Data requirements remain outstanding for this product.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Lindane Guidance Document dated 9/85 requires only octanol/water partition coefficient data (Guideline Reference No. 63-11) for the technical grade of the active ingredient (TGAI). However updated requirements include the following additional physicochemical characteristics for manufacturing-use products (MPs): oxidizing/reducing action, flammability, explosability,

storage stability, viscosity, miscibility, and corrosiveness (Guideline Reference Nos. 63-14 through 20). Since all the registered technical products are solids, flammability, viscosity, and miscibility are not applicable.

CIEL member Rhone-Poulenc submitted octanol/water partition coefficient data (1986; MRID 00160130) for the 99.5% Ts (EPA Reg. Nos. 264-454 and 264-455). The average log of K_{ow} is 3.50 (a partition coefficient of 3135 ± 990). The analytical method used to determine the coefficient was thoroughly presented in the submission. These data satisfy the requirements of 40 CFR §158.190 (Guideline Reference No. 63-11) for the Rhone-Poulenc 99.5% T's (EPA Reg. Nos. 264-454 and 264-455), the EM Industries 99.5% T (EPA Reg. No. 21137-3), the Inquinosa 99.5% T (EPA Reg. No. 40083-1), the Prentiss 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393), the Amvac 99.5% T (EPA Reg. No. 5481-225), and the Management Contract Services 100% T and 99.5% T (EPA Reg. Nos. 63823-12 and 63823-13). Data pertaining to oxidizing/reducing action, explodability, storage stability, and corrosiveness remain outstanding for all the products listed above.

No data pertaining to physicochemical properties have been submitted for the Trical 99% T (EPA Reg. No. 11220-19) and the Drexel 99.5% Ts (EPA Reg. Nos. 1973-191 and 19713-61). The following data requirements remain outstanding for these products: octanol/water partition coefficient, oxidizing/reducing action, explodability, storage stability, and corrosiveness.

Product Chemistry Citations (used):

00160127 Inquinosa (19??) Synthesis of Lindane. Unpublished study. 4 p.

00160128 Rhone-Poulenc Inc. (1986) Synthesis of Lindane. Unpublished study. 4 p.

00160129 Buys, M. (1986) Lindane...Product Identity and Composition... Discussion of the Formation of Impurities: Report AG/CRLD/AN/MB/ID/15274.86. Unpublished study prepared by Rhone-Poulenc Agrochimie. 10 p.

00160130 Mirfakhrae, K.; Norris, F. (1986) Determination of the Octanol/Water Partition Coefficient of Lindane: Ref. No. 86/BHL/191/AG: ASD No. 86/187. Unpublished study prepared by Rhone-Poulenc Inc. 26 p.

00164198 Drexel Chemical Co. (1986) Drexel Lindane 99.5% Technical: :Product Chemistry Data:. Unpublished study. 15 p.

00164782 Viziere, G. (1986) Lindane: Analysis and Certification of Product Ingredients: AG/CRLD/AN/MB/ID/15871.86. Unpublished study prepared by Rhone-Poulenc Agrochimie. 57 p.

00164783 Buys, M. (1986) Lindane: Analytical Data for the Technical Grade Lindane Produced by Inquinosa: Report AG/CRLD/AN/MB/ID/158874.86. Unpublished study prepared by Rhone-Poulenc Agrochimie. 9 p.

Product Chemistry Citations (not used):

These MRIDs pertain to end-use products or, in the case of MRID 00157343, a cancelled product.

00145806 Chipman Inc. (19??) :Product Chemistry of Agrox S Sunflower Seed Treatment Insecticide-Fungicide:. Unpublished study. 1 p.

00157343 Sumitomo Corp. of America. (1986) The Specification and Method of Analysis of Lindane. Unpublished study. 8 p.

00160363 Tucker, D., comp. (1986) Product Chemistry in Support of Registration of Lindane 20 EC. Unpublished compilation prepared by Micro Flo Co. 83 p.

00161845 O-Cal Chemical Co., Inc. (1986) C.I.A. Lab Preliminary Analysis and Product Specific Data Report: :Lindane:. Unpublished compilation. 6 p.

00162211 Espoy, H. (1986) :Product Chemistry Data for 13% Lindane, 021585:. Unpublished study prepared by Associated Laboratories. 2 p.

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

00162620 Espoy, H. (1986) :Product Chemistry of Terminate Flowable Termiticide Concentrate:: Lab No. F14247. Unpublished study prepared by Orion Chemical. 2 p.

00164940 Mote, J.; Rosa, F.; Wurther, C. (1986) Product Chemistry Data: Gustafson Vitavax-diazinon-lindane Seed Treatment: Laboratory Project Id. R101:45. Unpublished study prepared by Gustafson, Inc. 15 p.

40195301 Lemm, J. (1986) Product Identity and Composition: :Rockland Tree & Shrub Spray:. Unpublished study prepared by OK Analytical Laboratories. 4 p.

40292201 Westerterp, P.; Lawson, M. (1987) Granol Plus Insecticide and Fungicide Cereal Seed Treatment: Product Stability Evaluation Report. Unpublished study prepared by Chipman. 3 p.

40421501 Knowlton, L.; Atsma, B. (1987) Lindane 20 - Product Chemistry Data: Code No. EXP87003. Unpublished compilation prepared by Universal Cooperatives, Inc. 14 p.

40562901 Wurz, J. (1988) Product Chemistry for Bonide Crotox II Seed Protector. Unpublished study prepared by Bonide Chemical Co., Inc in conjunction with Syracuse University. 21 p.

40819001 Lail, L. (1988) Agrox Super: Product Chemistry: Study No. PC-88-014. Unpublished study prepared by Ciba-Geigy Corp. 95 p.

40833601 Wurz, J. (1988) Product Chemistry for Bonide Lawn de Gruber. Unpublished study prepared by Bonide Chemical Co., Inc. in cooperation with Utica College of Syracuse Univ. 15 p.

41006401 Rosa, F.; McArdle, T. (1988) Storage Stability Data: Gustafon Vitavax-Diazinon-Lindane Seed Treatment: Project ID No. 89-007. Unpublished study prepared by Trace Chemical Co., Inc. 10 p.

41427901 Mote, J.; Rosa, F.; Dempsay, A. (1990) Product Chemistry Data: Gustafson Vitavax-Thiram-Lindane Flowable Fungicide-Insecticide: Lab Project Number: R208:99-1:IVQD. Unpublished study prepared by Gustafson, Inc. 55 p.

41339801 Tucker, D.; comp. (1986) Product Chemistry for Lindane
20 EC: Lab Project ID: LINDANE 20 EC. Unpublished study prepared
by Thornton Laboratories. 95 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE LINDANE 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)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-2. Beginning Materials and Production Process	TGAI	Partially	<u>00160127</u> <u>00160128</u> <u>00164198</u>	Yes ⁴
61-3. Formation of Impurities	TGAI	Partially	<u>00160129</u>	Yes ⁵
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis	TGAI	Partially	<u>00164782</u> <u>00164783</u> <u>00164198</u>	Yes ⁶
<u>Physical and Chemical Characteristics⁷</u>				
63-2. Color	TGAI	Yes	N/A	No
63-3. Physical State	TGAI	Yes	N/A	No
63-4. Odor	TGAI	Yes	N/A	No
63-5. Melting Point	TGAI	Yes	N/A	No
63-6. Boiling Point	TGAI	N/A	N/A	No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	N/A	No
63-8. Solubility	TGAI or PAI	Yes	N/A	No
63-9. Vapor Pressure	TGAI or PAI	Yes	N/A	No
63-10. Dissociation Constant	TGAI or PAI	N/A	N/A	No
63-11. Octanol/Water Partitioning Coefficient	PAI	Partially	<u>00160130</u>	Yes ⁸
63-12. pH	TGAI	N/A	N/A	No
63-13. Stability	TGAI	Yes	N/A	No
<u>Other Requirements:</u>				
64-1. Submittal of Samples	N/A	N/A	N/A	No

1. Data requirements pertain to the following products: Rhone-Poulenc Ag Company, Inc. 99.5% Ts (EPA Reg. Nos. 264-454 and 264-455), EM Industries, Inc. 99.5% T (EPA Reg. No. 21137-3), Inquinsa 99.5% T (EPA Reg. No. 21137-3).

TABLE A. (Continued).

- No. 40083-1), Prentiss Drug and Chemical Co. 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393), Amvac Chemical Corp. 99.5% T (EPA Reg. No. 5481-225), Trical 99% T (EPA Reg. No. 11220-19), Drexel Chemical Co. 99.5% Ts (EPA Reg. Nos. 19713-61 and 19713-191), and Management Contract Services, Inc. 100% and 99.5% Ts (EPA Reg. Nos. 63823-12 and 63823-13, respectively). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Lindane Manufacturing-Use Products".
2. Test substance: PAI = purified active ingredient; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.
 3. Underlining indicates documents that have been reviewed in this Update Document.
 4. Registrants have not responded to the data requirements for the Trical 99% T and the Drexel 99.5% T (EPA Reg. No. 19713-61). All data concerning this topic are required for these products. Rhone-Poulenc and Inquinsa have responded for their 99.5% Ts; however the following additional data must be submitted: (i) amounts and order in which the starting materials were added; (ii) clarification of whether the process is a batch or continuous process; (iii) duration of each step and the total process; (iv) description of the equipment used in the process; and (v) quality control measures used to ensure the integrity of the product. Once data requirements have been satisfied, these data will also apply to the following products: EM 99.5% T, Prentiss 99.5% Ts, Amvac 99.5% T, and Management Contract Services 100% and 99.5% Ts. Drexel has responded for the 99.5% T (EPA Reg. No. 19713-191); however the following additional data are required: (i) technical specifications and suppliers for all starting materials; (ii) amounts and order in which the starting materials were added; (iii) clarification of whether the process is a batch or continuous process; (iv) duration and controlled parameters (temperature, humidity, and pressure) of each step and the total process; (v) description of the equipment used in the process; and (vi) quality control measures used to ensure the integrity of the product.
 5. Registrants have not responded to the data requirements for the Trical 99% T and the Drexel 99.5% Ts. All data concerning this topic are required for these products.
 6. Registrants have not responded to the data requirements for the Trical 99% T and the Drexel 99.5% T (EPA Reg. No. 19713-61). All data concerning this topic are required for these products. Rhone-Poulenc and Inquinsa have responded for their 99.5% Ts; however, the registrants must establish that the method used for analysis of dioxins and dibenzofurans can quantitate the reference standard, 2,3,7,8-TCDD to 0.1 ppb. Once data requirements have been satisfied, these data will also apply to the EM 99.5% T, Prentiss 99.5% Ts, Amvac 99.5% T, and Management Contract Services 100% and 99.5% Ts. Drexel has responded for the 99.5% Ts

TABLE A. (Continued).

(EPA Reg. No. 19713-191); however, the registrant must submit preliminary analysis of each impurity present at 0.1% or greater and analysis of dioxins at the levels described in the dioxin data call-in.

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. Registrants have not responded to the data requirements for the Trical 99% T and the Drexel 99.5% Ts. Data on octanol/water partition coefficient are required if the technical chemical is organic and nonpolar.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR LINDANE 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)?
<u>40 CFR 158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-1. Product Composition	MP	Partially	N/A	Yes ⁴
61-2. Beginning Materials & Production/Formulation Process	MP	Partially	00160127 00160128	Yes ⁵
61-3. Formation of Impurities	MP	Partially	00164198	Yes ⁶
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis	MP	Partially	00164782 00164783	Yes ⁷
62-2. Certified Limits	MP	Partially	00164198	Yes ⁸
62-3. Enforcement Analytical Methods	MP	Partially	00164198 00164782	Yes ⁹
<u>Physical and Chemical Characteristics¹⁰</u>				
63-2. Color	MP	Yes	N/A	No
63-3. Physical State	MP	Yes	N/A	No
63-4. Odor	MP	Yes	N/A	No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	N/A	No
63-12. pH	MP	N/A	N/A	No
62-14. Oxidizing or Reducing Action	MP	No	N/A	Yes ¹¹
62-15. Flammability	MP	N/A	N/A	No
63-16. Explodability	MP	No	N/A	Yes ¹²
63-17. Storage Stability	MP	No	N/A	Yes ¹³
63-18. Viscosity	MP	N/A	N/A	No
63-19. Miscibility	MP	N/A	N/A	No
63-20. Corrosion Characteristics	MP	No	N/A	Yes ¹³
<u>Other Requirements:</u>				
64-1. Submittal of Samples	N/A	N/A	N/A	No

TABLE B. (Continued).

1. Data requirements pertain to the following products: Rhone-Poulenc Ag Company, Inc. 99.5% Ts (EPA Reg. Nos. 264-454 and 264-455), EM Industries, Inc. 99.5% T (EPA Reg. No. 21137-3), Inquinsa 99.5% T (EPA Reg. No. 40083-1), Prentiss Drug and Chemical Co. 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393), Amvac Chemical Corp. 99.5% T (EPA Reg. No. 5481-225), Trical 99% T (EPA Reg. No. 11220-19), Drexel Chemical Co. 99.5% Ts (EPA Reg. Nos. 19713-61 and 19713-191), and Management Contract Services, Inc. 100% and 99.5% Ts (EPA Reg. Nos. 63823-12 and 63823-13, respectively). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Lindane Technical Grade of the Active Ingredient".
2. Test substance: PAI = purified active ingredient; TCAI = technical grade of the active ingredient; MP = manufacturing-use product.
3. Underlining indicates documents that have been reviewed in this Update Document.
4. Current Confidential Statements of Formula (CSFs) were unavailable for review for the following products: both Rhone-Poulenc 99.5% Ts, Inquinsa 99.5% T, Trical 99% T, and both Drexel 99.5% Ts. Updated CSFs are required for proper evaluation of product chemistry data for each product. EM has submitted an updated CSF for its 99.5% T; however, the identity, purpose, and nominal concentration must be submitted for each inert ingredient present at $\geq 0.1\%$. Registrants have submitted updated CSFs for the Amvac 99.5% T and the Management Contract Services 99.5% T and 100% T; however, for each product, the nominal concentration of the active ingredient must be based on the nominal concentration of the active ingredient in the technical source product.
5. Registrants have not responded to the data requirements for the Trical 99% T and the Drexel 99.5% T (EPA Reg. No. 19713-61). All data concerning this topic are required for these products. Rhone-Poulenc and Inquinsa have responded for their 99.5% Ts; however the following additional data must be submitted: (i) amounts and order in which the starting materials were added; (ii) clarification of whether the process is a batch or continuous process; (iii) duration of each step and the total process; (iv) description of the equipment used in the process; and (v) quality control measures used to ensure the integrity of the product. Once data requirements have been satisfied, these data will also apply to the following products: EM 99.5% T, both Prentiss 99.5% Ts, Amvac 99.5% T, and Management Contract Services 100% and 99.5% Ts. Drexel has responded for the 99.5% T (EPA Reg. No. 19713-191); however the following additional data are required: (i) technical specifications and suppliers for all starting materials; (ii) amounts and order in which the starting materials were added; (iii) clarification of whether the process is a batch or continuous process; (iv) duration and controlled parameters (temperature, humidity, and pressure) of each step and the total

TABLE B. (Continued).

process; (v) description of the equipment used in the process; and (vi) quality control measures used to ensure the integrity of the product.

6. Registrants have not responded to the data requirements for the Trical 99% T and the Drexel 99.5% Ts. All data concerning this topic are required for these products.

7. Registrants have not responded to the data requirements for the Trical 99% T and the Drexel 99.5% T (EPA Reg. No. 19713-61). All data concerning this topic are required for these products. Rhone-Poulenc and Inquinosa have responded for their 99.5% Ts; however, the registrant must establish that the method used for analysis of dioxins and dibenzofurans can quantitate the reference standard, 2,3,7,8-TCDD to 0.1 ppb. Once data requirements have been satisfied, these data will also apply to the EM 99.5% T, both Prentiss 99.5% Ts, Amvac 99.5% T, and Management Contract Services 100% and 99.5% Ts. Drexel has responded for the 99.5% T (EPA Reg. No. 19713-191); however, the registrant must submit preliminary analysis of each impurity present at 0.1% or greater and analysis of dioxins at the levels described in the dioxin data call-in.

8. Registrants have not responded to the data requirements for the following products: the EM 99.5% T, Inquinosa 99.5% T, Trical 99% T, and one of the Drexel 99.5% Ts (EPA Reg. No. 19713-61). All data concerning this topic are required for these products. Rhone-Poulenc has responded for its 99.5% Ts; however, an upper certified limit must be submitted for the active ingredient. Amvac has responded for the 99.5% T; however, specific certified limits must be proposed for the active ingredient in this product, instead of the certified limits referenced for the active ingredient in the technical source product. Management Contract Services have responded for the 99.5% T and 100% T; however, certified limits for the active ingredient must be based on the nominal concentration of the active ingredient in the source product rather than the amount of source product used. In addition, Management Contract Services must include the new registrant and registration numbers, and certify that the manufacturing location and process have not changed for their 99.5% T and 100% Ts. All updated certified limits must be submitted on EPA Form 8570-4 (Rev. 2-85).

9. Trical has not responded to the data requirements for the 99% T. All data concerning this topic are required for this product. Rhone-Poulenc has responded for its 99.5% Ts and the analytical methods are adequate; however, if the registrant intends to select the CIPAC cryoscopic method for enforcement then a complete description of the method and validation data will be required. These data also apply to the following products: EM 99.5% T, Inquinosa 99.5% T, both Prentiss 99.5% Ts, Amvac 99.5% T, and Management Contract Services 100% and 99.5% Ts. Drexel has responded for the 99.5% Ts; however, validation data are required for the analytical method submitted and enforcement analytical methods must be submitted for

22

TABLE B. (Continued).

impurities of toxicological concern. In addition, because further data are required for this product pertaining to discussion of impurities and preliminary analysis, additional impurities of toxicological concern may be identified and additional enforcement analytical methods may be required.

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, explosibility, 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 Lindane Technical Grade of the Active Ingredient."

11. None of the registrants listed in footnote 1 have responded to data requirements for their lindane technical products; data are required on oxidizing/reducing potential if the product contains an oxidizing or reducing agent.

20

12. None of the registrants listed in footnote 1 have responded to data requirements for their lindane technical products; data are required if the product is potentially explosive.

13. None of the registrants listed in footnote 1 have responded to data requirements for their lindane technical products; all data concerning this topic are required.

LINDANE
REGISTRATION STANDARD UPDATE
PRODUCT CHEMISTRY
TASK 4
(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 8 Page(s)
Appendix B: 2 Page(s)
Appendix C: 2 Page(s)
Appendix D: 3 Page(s)
Appendix E: 1 Page(s)

Confidential Appendices to the Scientific Review of the Registration Standard Update Report for the pesticide lindane by the Dietary Exposure Branch [Confidential FIFRA Trade Secret/CBI].

RIN 1083-95

LINDANE CHEMISTRY REVIEW

Page is not included in this copy.

Pages 75 through 40 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- ✓ Identity of product impurities.
- ✓ Description of the product manufacturing process.
- ✓ Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) .
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Final Report

LINDANE
Task 4: Residue Chemistry
Registration Standard Update

January 18, 1991

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

LINDANE

REGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 4

Table of Contents

	Page
INTRODUCTION	1
SUMMARY	2
QUALITATIVE NATURE OF THE RESIDUE IN PLANTS	3
QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS	4
RESIDUE ANALYTICAL METHODS	6
STORAGE STABILITY DATA	8
MAGNITUDE OF THE RESIDUE IN PLANTS	9
Leafy Vegetables Group	10
Lettuce	10
Brassica Leafy Vegetables Group	12
Cabbage	12
Cucurbit Vegetables Group	14
Cucumber	14
Pome Fruits Group	16
Apples	16
Stone Fruits Group	18
Peaches	18
Small Fruits and Berries Group	20
Grapes	20
Tree Nuts Group	23
Pecans	23
Miscellaneous Commodities	24
Tobacco	24
Crops with Seed Treatments Only	26
MAGNITUDE OF THE RESIDUE IN MEAT, MILK, POULTRY, AND EGGS . .	32
Milk and Meat, Fat, and By-products of Cattle, Goats,	
Hogs, Horses, and Sheep	32
Eggs and the Fat, Meat, and Meat Byproducts of Poultry .	34
MASTER RECORD IDENTIFICATION NUMBERS	35
TABLE A. GENERIC DATA REQUIREMENTS FOR LINDANE	42

LINDANE

REGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 4

INTRODUCTION

The 8/11/89 Update of the Index of Pesticide Chemicals identifies registered food/feed uses for the insecticide lindane on the following crops: apple, apricots, broccoli, Brussels sprouts, cabbage, cantaloupes, cauliflower, celery, cherries, collards, cucumbers, cucurbits, grapes, kale, lettuce, melons, okra, onions (dry bulb only), peas, peaches, pears, pecans, peppers, plums (fresh prunes), pumpkins, spinach, squash, tomatoes, and watermelons. Lindane formulations are also registered for: (i) seed treatment use on alfalfa, barley, beans (including succulent and lima beans), beets, broccoli, Brussels sprouts, cabbage, cantaloupes, carrots, clover, corn (field, sweet, and popcorn), cotton, cucumbers, flax, lentils, lettuce, oats, okra, onions (dry bulb only), peas, pumpkins, radishes, rye, safflower, small grains, sorghum, soybeans, spinach, squash, sudangrass, sugar beets, sunflower, tomatoes, watermelons, and wheat; and (ii) for use on tobacco. Formulations registered for seed treatment, bark, foliar, delayed dormant, preplant and postplant soil applications, premises and animal treatment (including bath or wash, back rubber, dip, dust, sponge on, and spray) include the 1-25% dust (D), the 1-75% wettable powder (WP), the 1-75% WP/D, the 0.87-2 lb/gal emulsifiable concentrate (EC), the 0.5-40% EC, the 4 lb/gal flowable concentrate (FLC), the 6.45-40% FLC, the 0.36 lb/gal soluble concentrate/liquid (SC/L), the 2.5-12.6% SC/L, the 1.01 lb/gal ready-to-use (RTU), the 0.1-10.5% RTU, and the 1 and 3% pressurized liquid (PrL) formulations.

The Lindane Guidance Document dated September, 1985 identifies outstanding data gaps for plant and animal metabolism; residue analytical methods (reserved); storage stability data; magnitude of the residue in apples, apricots, asparagus, avocados, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherries, collards, cucumbers, eggplant, guavas, grapes, kale, kohlrabi, lettuce, mangoes, melons, mushrooms, mustard greens, nectarines, okra, onions (dry bulb only), peas, peaches, pears, pecans, peppers, pineapples, plums (fresh prunes), pumpkins, quince, spinach, strawberries, squash, Swiss chard, tobacco, and tomatoes, and for the following crops for seed treatment only (alfalfa, barley, beans (succulent and dry), beets, carrots, clover, corn (field, sweet, and popcorn), cotton, flax, lentils, oats, radishes, rye, safflower, sorghum, soybeans, sudangrass, sugar beets, sunflowers, and wheat), and in the processed products of apples, cotton, grapes, pineapples, sunflower seeds,

soybeans, and tomatoes; and the magnitude of the residues in meat, milk, poultry, and eggs.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted 16 volumes of data pertaining to the nature of the residues in plants (MRIDs 40410902, 40431201, and 40431204), nature of the residues in animals (MRIDs 40271301 and 40271302), residue analytical methods (MRIDs 40431202, 40431206, and 40431208), storage stability data (MRIDs 40431203, 40431205, and 40660502), magnitude of the residue in plants (MRID 40431207), and magnitude of the residues in animals (MRIDs 40660501, 40660503, 40660504, and 40660505) which have been reviewed by the Agency. In addition, Rhône-Poulenc AG Co. submitted 11 volumes of data pertaining to magnitude of the residues in apples (MRIDs 41289401 and 41289402), cabbage (MRID 41289403), cucumbers (MRID 41289404), grapes (MRIDs 41289405 and 41289406), lettuce (MRID 41289407), peaches (MRID 41289408), pecans (MRIDs 41289601 and 41421001), and tobacco (MRID 41289409) which are reviewed in this update for their adequacy in fulfilling the outstanding data requirements. The available data up to 9/27/90 have been included in this update.

Tolerances for lindane residues in or on food and feed commodities and animal products are currently expressed in terms of residues of lindane (gamma isomer of benzene hexachloride) [40 CFR §180.133].

SUMMARY

The following Lindane residue chemistry data are required:

- Additional data pertaining to plant and animal metabolism, residue analytical methods, and storage stability.
- Tolerances must be proposed and supporting residue data submitted for alfalfa, clover, barley, beans, beets, radishes, carrots, corn, cotton, oats, rye, sorghum, wheat, flax, lentils, peas, safflower, soybeans, sudangrass, sugar beets, and sunflower for which seed treatments are registered.
- Additional residue data are required for lettuce, cabbage, cucumber, apple, peaches, grapes, pecans, and tobacco.
- Additional processing data are required for apples and grapes.
- The registrants 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 submitted data must reflect these specifications.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The Lindane Guidance Document dated September, 1985 concludes that the qualitative nature of the residue in plants is not adequately delineated and requires additional data concerning the metabolism of [¹⁴C]lindane (polar and non-polar metabolites) in representative crops from three crop groupings (cucurbits, leafy vegetables, and a pome or stone tree fruit). In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data pertaining to the metabolism of [¹⁴C]lindane in apples (1987; MRID 40410902), cucumbers (1987; MRID 40431204), and spinach (1987; MRID 40431201) which were reviewed by DEB (EPA Memorandum DEB No. 3267, G. Otakie, dated 3/24/88). It was concluded that the nature of the residue in plants is not adequately understood. In the study with apples, residues identified in the mature fruit include: lindane (10.9% of the TRR), pentachlorophenol (13.6%), 2,4,5-trichlorophenol (0.3%), and 2,3,4,5-tetrachlorophenol (0.3%). Other metabolites identified in apple foliage or immature fruit are 2,3-dichlorophenol, 2,4-dichlorophenol, 2,3,5-trichlorophenol, 2,4,6-trichlorophenol, and 2,3,5,6-tetrachlorophenol. In the studies with cucumbers and spinach respectively, 90 and 99% of the applied radioactivity was lost to the air within 4 or 7 days posttreatment. Lindane was the only compound identified in the extractable fraction from spinach leaves, cucumber leaves, and cucumber fruit. DEB requested additional information concerning sample history (watering procedure, calibration and application of [¹⁴C]lindane), storage time and conditions, numerical radioactivity data before and after extraction, legible and identified copies of HPLC chromatographs, and confirmation of metabolites identified by TLC. In addition, the registrant should address the issue of the potential loss of volatile metabolites when samples are concentrated to dryness. The following additional data are required:

- Additional data are required to verify the results reported in the submitted metabolism studies on apples, cucumbers, and spinach (MRIDs 40410902, 40431204, and 40431201): (i) total radioactive residues before and after extraction and of the remaining solid residue subjected to combustion; (ii) storage intervals and conditions of frozen storage including the period before frozen storage, extraction, clean up and analysis; (iii) confirmation of the level of lindane and any

metabolite identified by TLC using GLC/MS; (iv) an explanation of the significant variation in the total ¹⁴C-residues found in mature apples from combustion/LSS compared to extraction/LSS; (v) an alternative procedure for concentrating the samples to dryness in order to prevent possible volatilization of metabolites; and vi) legible copies of spray test calibrations, HPLC chromatograms, and GLC-MS results. 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. New radiolabeled metabolism studies conducted at exaggerated rates and including acidic, basic and enzymatic hydrolysis to release conjugated residues may be necessary to adequately characterize metabolites. If metabolism data differ significantly among these crops, then metabolism data will be required for a representative crop from each crop grouping for which there is a registered tolerance.

The available data concerning plant metabolism, although inadequate, suggest that lindane is converted to 2,3-dichlorophenol, 2,4-dichlorophenol, 2,3,5-trichlorophenol, 2,4,5-trichlorophenol, 2,4,6-trichlorophenol, 2,3,4,5-tetrachlorophenol, 2,3,5,6-tetrachlorophenol, and pentachlorophenol.

References (used):

MRID(s): 40410902. 40431204. 40431201.

Discussion of the data:

N/A.

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The Lindane Guidance Document dated September, 1985 concludes that the nature of the residue in animals is not adequately understood and that additional ruminant and poultry metabolism studies are required. In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1987; MRID 40271302) pertaining to metabolism of [¹⁴C]lindane in lactating goats which were reviewed by DEB (EPA Memorandum DEB No. 3312, C. Deyrup, dated 3/24/88) who concluded that the nature of the residue in ruminants is not adequately understood. The registrant needs to submit a more complete characterization of the TRR in the liver and kidney of ruminants. Only 4.5-7.0% of the TRR in kidney and

0.3-0.7% in liver was identified. The ten metabolites identified in goat tissues and milk must be confirmed by GLC/MS. TOX (EPA Memorandum TOX Chem No. 527, J. Doherty, dated 5/19/88) stated that the registrant should identify liver and kidney metabolites, determine the approximate half life of the total residue in these organs, and verify that analytical methods are available to determine the residue in these and other organs. TOX also noted that the kidney is of special concern because it has been identified as a target organ for lindane toxicity. Regarding the oral goat metabolism study, the registrant must submit the raw data and explain the inconsistencies in some of the reported residue levels. The following additional data are required:

- For the metabolism study in lactating goats reflecting oral and topical application (MRID 40271302): (i) data depicting a more complete characterization of the TRR in the liver and kidney of ruminants; (ii) additional information to verify the dosages used in the oral goat metabolism study; (iii) data concerning the raw radiometric data for all the various fractions, zones corresponding to identified metabolites, and matrix samples; (iv) confirmation of the identities of the residues by GLC/MS; (v) explanation of the inconsistencies in some of the reported residue levels; (vi) additional chromatograms and recovery data for the expected metabolites from additional goat matrices; and (vii) a Kuderna-Danish concentrator should be used during the concentration step instead of a rotary evaporator.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1987; MRID 40271301) pertaining to metabolism of [¹⁴C]lindane in laying hens which was reviewed by DEB (EPA Memorandum DEB No. 3315, J.H. Onley, dated 3/24/88) who has concluded that the nature of the residue in poultry is partially understood for exposure up to 4 days, but not understood for long-term exposure. DEB requests the registrant to submit raw data/calculations, GLC chromatograms, and confirmation of the terminal residues by GLC/MS. In addition, since lindane residues did not plateau in eggs after 4 and 6 days of dosing, a combination long-term [¹⁴C]lindane metabolism/feeding study is needed after determination of residues of toxicological concern. DEB also suggests that a Kuderna-Danish concentrator should be used during the concentration step instead of a rotary evaporator to prevent loss of metabolites with early GLC retention times. The following additional data are required:

- For the poultry metabolism study (MRID 40271301): (i) data concerning raw data/calculations, GLC chromatograms, and confirmation of terminal residues by GLC/MS; (ii) since lindane residues did not plateau in egg yolk after 4 and 6 days of dosing, a combination long-term [¹⁴C]lindane metabolism/feeding study is needed after

determination of residues of toxicological concern; and
(iii) a Kuderna-Danish concentrator should be used during
the concentration step instead of a rotary evaporator.

The available data pertaining to metabolism in ruminants and poultry, although incomplete, suggest that lindane is converted to 1,2,4-, 1,3,5-, and 1,2,3-trichlorobenzene; 1,2,3,4-, 1,2,4,5-, 1,2,3,5-, and 1,2,4,5-tetrachlorobenzene; 2,3,4,5,6-pentachlorocyclohexene; 1,2,3,4,5-pentachlorobenzene; hexachlorobenzene; hexachlorocyclohexene; 4-chlorophenol; 2,4-, 2,5-, 2,6-, and 3,4-dichlorophenol; 2,3,5-, 2,4,5-, 2,3,6-, and 2,4,6-trichlorophenol; 2,3,4,5-, 2,3,5,6-, and 2,3,4,6-tetrachlorophenol.

References (used):

MRID(s): 40271301. 40271302.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Conclusions:

The qualitative nature of the residue in plants and animals has not been adequately described. Therefore, the adequacy of the available analytical methods cannot be ascertained. The Lindane Guidance Document dated September, 1985 concludes that adequate methodology is available only for the analysis of the parent compound, lindane. If the required plant and animal metabolism studies establish that other residues of toxicological concern are present in plant or animal commodities, appropriate analytical methodology must be developed and validated.

Adequate methodology is available for analysis of lindane in AOAC Group I nonfatty crops such as spinach and cucumber, dairy products, fish, and eggs. In addition, Rhône-Poulenc AG Co. submitted data for residue analytical methods for detection of lindane per se in cucumbers (1987; MRID 40431202) and spinach (1987; MRID 40431206), which were reviewed by DEB (EPA Memorandum DEB No. 3257, N. Dodd, dated 3/24/88). The analytical procedures for detecting lindane in cucumbers and spinach are essentially the same, lindane is extracted with acetonitrile, partitioned with hexane-acetonitrile, cleaned up using Florisil column chromatography, and analyzed by gas chromatography with electron capture detection (ECD). Recoveries were 87.2-105.5% and 86.8-105.9%, respectively, from cucumber and spinach samples fortified with lindane at 0.1-1 ppm. The limit of detection is 0.01 ppm for lindane. DEB has concluded that this method is

adequate for determining residues of lindane (parent compound) in nonfatty crops.

Rhône-Poulenc AG Co. also submitted an analytical method for detection of residues of lindane in animal tissues, eggs, and milk (1987; MRID 40431208), which was reviewed by DEB (EPA Memorandum DEB No. 3261, N. Dodd, dated 3/24/88). It was concluded that the proposed methodology for animal commodities contains some techniques, such as use of gel permeation chromatography and rotary evaporation, which are not described in Official Methods of Analysis (AOAC). Therefore, if lindane tolerances are to be established for lean animal tissues, an EPA method validation would be needed to determine whether the submitted method is adequate for enforcement purposes. However, if it is decided that lindane metabolites are of toxicological concern after the plant and animal metabolism issues have been resolved, then the registrant will need to make some modifications in this methodology or develop new methodology that will determine these metabolites.

The FDA Pesttrak database (PAM, Vol. I, Appendix dated 12/13/89) contains data concerning the applicability of multiresidue methods to lindane. Lindane is completely recovered (>80%) using protocols D (232.4) and E (211.1 and 212.1) for nonfatty and fatty food, respectively.

Data collected on plant commodities submitted in response to the Guidance Document used a method for analysis of lindane described in the General Multi-Residue Methodology (AOAC, Official Methods of Analysis, 14th Edition, 1984). This method is similar to the method described in the Lindane Guidance Document dated September, 1985, as Method AOAC, 13th Edition, 1980. By this method, non-fatty foods are extracted with acetonitrile and fat containing foods such as animal and vegetable fats and oil, butter, milk, cheese, and fish are partitioned with acetonitrile, after isolation of the fat. For fatty and non-fatty foods, an aliquot of the extracted sample is diluted with water and concentrated in Kuderna-Danish concentrators. Residues are extracted into petroleum ether, purified using a florisil column, and eluted with a mixture of petroleum ether and ethyl ether. Residues in concentrated eluates are measured by GLC/ECD, with a limit of detection of 0.005 ppm. Oilseed samples are extracted with petroleum ether, concentrated, reextracted with ethyl alcohol, mixed with concentrated sodium hydroxide, cleaned up by a Florisil column chromatography, and analyzed as described above. The following data remain outstanding:

- The qualitative nature of the residue in plants and animal has not been adequately described; therefore, the adequacy of the available methods cannot be ascertained. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of

toxicological concern, data depicting additional analytical methods will be required. Representative samples from plant and animal metabolism studies must be analyzed using currently accepted or proposed enforcement methodology in order to determine that these methods are capable of recovering all residues of concern.

References (used):

MRID(s): 40431202. 40431206. 40431208.

Discussion of the data:

N/A.

STORAGE STABILITY DATA

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data delineating the stability of lindane residues in or on representative crops from three crop groupings (cucurbits, leafy vegetables, and a tree fruit, stone or pome fruit). Data describing the stability of lindane in at least one animal commodity are also required. If the required plant and animal metabolism studies indicate the occurrence of residues of toxicological concern (in addition to the parent lindane) additional storage stability data on these residues will also be required.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data concerning the storage stability of lindane in fortified spinach (1987; MRID 40431203) and cucumbers (1987; MRID 40431205), which were reviewed by DEB (EPA Memorandum DEB No. 3260, N. Dodd, dated 3/24/88). DEB has concluded that storage stability data for lindane on cucumbers and spinach are adequate for storage up to 8 months. However, no data were submitted for a tree fruit (pome or stone). Rhône-Poulenc AG Co. also submitted storage stability data for fortified chicken, beef, egg, and milk samples (MRID 40660502), which were reviewed by DEB (EPA Memorandum DEB No. 4035, S.H. Willett, dated 8/23/88). DEB has concluded that lindane is stable in animal tissues, eggs, and milk stored at -18 C for 9 months. DEB also notes that additional data may be necessary for metabolites found to be of toxicological concern. The following data requirements remain outstanding:

- The sample storage intervals and conditions must be supplied for all residue data submitted in support of tolerances, whether previously submitted or required in this update. Storage stability studies in support of

previously submitted residue data must reflect the actual storage conditions and intervals for samples used to generate the residue data. If residue depletion occurs, data will be required which depict the decline in levels of lindane residues of concern in commodities stored under the range of conditions and for the range of intervals specified. Tree fruit samples (pome or stone) bearing measurable, weathered residues or fortified with lindane residues of concern, and fortified meat or milk samples must be analyzed immediately after harvest or fortification and again after storage intervals that allow for reasonable unforeseen 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 on 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):

MRID(s): 40431203. 40431205. 40660502.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN PLANTS

NOTE TO SRRD: Tolerances currently exist for residues of lindane in or on asparagus, avocados, guavas, kohlrabi, mangos, mushrooms, mustard greens, nectarines, pineapples, quinces, and Swiss chard. Presently, however, there are no registered uses for lindane on these sites. Unless an interested party declares intent to include any of these use sites on a product label and to submit appropriate, supporting residue data, we recommend that these existing tolerances for lindane residues in or on these food/feed commodities be revoked.

The Lindane Guidance Document dated September, 1985 identifies outstanding data requirements for apples, apricots, asparagus,

avocados, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherries, collards, cucumbers, eggplant, guavas, grapes, kale, kohlrabi, lettuce, mangoes, melons, mushrooms, mustard greens, nectarines, okra, onions (dry bulb only), peas, peaches, pears, pecans, peppers, pineapples, plums (fresh prunes), pumpkins, quince, spinach, strawberries, squash, Swiss chard, tobacco, and tomatoes; and for the processed products of apples, cotton, grapes, pineapples, sunflower seeds, soybeans, and tomatoes. In addition, the Guidance Document requires proposed tolerances and appropriate supporting residue data for seed treatment only of alfalfa, barley, beans (succulent and dry), beets, carrots, clover, corn (field, sweet, and popcorn), cotton, flax, lentils, oats, radishes, rye, safflower, sorghum, soybeans, sudangrass, sugar beets, sunflowers, and wheat.

Rhône-Poulenc AG Co. responded to these requirements by submitting residue and/or processing data for apples, cabbage, cucumbers, grapes, lettuce, peaches, pecans, and tobacco. Data contained in Rhone-Poulenc's submissions are reviewed in this update document. However, these data are not evaluated for purposes of satisfying data requirements specified in the 9/85 Lindane Guidance Document because insufficient data are available to assess the adequacy of use directions on current product labels. Parties interested in retaining registered uses on crop sites must submit additional data. Residue data must reflect use directions and maximum registered application rates specified on current product labels.

The conclusions stated in this section regarding the adequacy of established tolerances may change on receipt of the required plant and animal metabolism, analytical method validation data, and storage stability data. Registrants should be urged to complete and submit all required plant and animal metabolism data, analytical method validation, and storage stability data prior to initiation of required field trials and processing studies.

Leafy Vegetables Group

Lettuce

Tolerance(s):

A tolerance of 3 ppm has been established for the residues of lindane (gamma isomer of benzene hexachloride) in or on lettuce [40 CFR §180.133].

Use directions and limitations:

The Agency Product Search Listing (SP05) dated 7/30/90 includes 25% D, 25% EC, 40% FLC, 75% WP/D, and 25 and 75% WP formulations registered for seed treatment use on lettuce, and 1.63 lb/gal EC,

10.68 and 20% EC, 25% WP/D, and 6 and 25% WP formulations registered for soil applications to lettuce.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting residues of lindane in or on lettuce (with and without wrapper leaves) following a treatment series including seed treatment, soil, and foliar applications, and, in a separate test, greenhouse fumigation with an Impr formulation. Also required are label amendments specifying a maximum seasonal application rate and a specific PHI for foliar applications. [Note: The 8/11/89 update to the Index does not list product registrations for either greenhouse fumigation or foliar application uses on lettuce; thus, residue data to support these uses are no longer required.]

In response to the Guidance Document, Rhône-Poulenc AG Co. (1989; MRID 41289407) submitted data indicating that residues of lindane in or on lettuce do not exceed the established 3 ppm tolerance when harvested 35-120 days following seed treatment with either the 40% FLC or 25% WP formulations at 0.0625 lb ai/100 lb seed, and preplant and posttransplant soil-directed applications with the 25% WP formulation at 0.5 lb ai/A. However, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on lettuce must submit the following additional data:

- Data depicting lindane residues of concern in or on lettuce harvested following seed treatment with a representative EC, FLC, or WP formulation and soil applications with a representative EC or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on lettuce must be conducted in CA(73%), CO(1%), FL(3%), NJ(1%), and TX(1%) since these states accounted for ca. 79% of the 1988 U.S. lettuce production (Vegetables, 1988 Summary, Agricultural Statistics Board, NASS, USDA June 1989, p. 12).

References (used):

MRID(s): 41289407.

Discussion of the data:

Rhône-Poulenc (1989; MRID 41289407) submitted data from seven tests conducted in CA, CO, FL, NJ, NY, TX, and WA pertaining to residues of lindane in or on lettuce harvested 35-120 days following the last of three applications including: (i) seed treatment with the 40% FLC (WA, only) or 25% WP formulation at 0.0625 lb ai/100 lb seed; (ii) a pre-transplanting, broadcast

incorporated soil application of the 25% WP formulation at 0.5 lb ai/A; and (iii) two weeks after transplanting, a post-directed soil application of the 25% WP formulation at 0.5 lb ai/A. Residues were <0.005 (nondetectable; ND)-0.028 ppm in or on 21 samples of head lettuce with wrapper leaves and <0.005 (ND)-0.03 ppm in or on 21 samples of head lettuce without wrapper leaves. Apparent residues in or on 14 untreated samples were <0.005 (ND)-0.009 ppm. Data were collected using a GLC/ECD method, with a limit of detection for lindane residues of 0.005 ppm. Recoveries of lindane were 76-114% from seven samples fortified with lindane at 0.01-1.59 ppm. Samples were stored frozen at ca. -20 to -23 C for 53-131 days prior to analysis.

Geographic representation is adequate since the test states of CA(73%), CO(1%), FL(3%), NJ(1%), NY(1%), TX(1%), and WA(<1%) accounted for ca. 80% of the U.S. lettuce production (Vegetables, 1988 Summary, Agricultural Statistics Board, NASS, USDA Jan 1989, p.46). The available data indicate that residues of lindane do not exceed the 3 ppm tolerance when harvested 35-120 days following seed treatment with either the 40% FLC or 25% WP formulations at 0.0625 lb ai/100 lb seed, and preplant and posttransplant soil-directed applications with the 25% WP formulation at 0.5 lb ai/A. However, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on lettuce must submit additional data.

Brassica Leafy Vegetables Group

Cabbage

Tolerance(s):

A tolerance of 1 ppm has been established for the residues of lindane (gamma isomer of benzene hexachloride) in or on cabbage [40 CFR §180.133].

Use directions and limitations:

The Agency Product Search Listing (SP05) dated 7/30/90 includes 25% D, 25% EC, 30 and 40% FLC, 4 lb/gal FLC, and 75% WP formulations registered for seed treatment use on cabbage, 1.63 lb/gal EC, 10.68, 12.5 and 20% EC, 25% WP/D, and 6 and 25% WP formulations registered for preplant and/or postplant soil applications to cabbage, and 20% EC, 25% WP, 25% WP/D, and 5% SLC formulations registered for foliar applications to cabbage.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting field residues of lindane in or on cabbage following a treatment series including seed treatment, soil, and foliar

applications. Also required are label amendments specifying a maximum seasonal application rate and a specific PHI for postplant soil applications.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1989; MRID 41289403) indicating that residues of lindane in or on cabbage do not exceed the established 1 ppm tolerance when harvested 56-152 days following seed treatment with either the 40% FLC or 25% WP formulations at 0.031 lb ai/100 lb seed, and preplant and posttransplant soil applications with the 25% WP formulation at 0.5 lb ai/A. However, no data were submitted reflecting foliar uses of lindane and insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on cabbage must submit the following additional data:

- Data depicting lindane residues of concern in or on cabbage harvested following seed treatment with a representative EC, FLC, or WP formulation, soil applications with a representative EC or WP formulation, and foliar application with a representative EC or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on cabbage 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 1982 U.S. cabbage acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 338).

References (used):

MRID(s): 41289403.

Discussion of the data:

Rhône-Poulenc (1989; MRID 41289403) submitted data from six tests conducted in CA, FL, GA, NY, TX, and WI pertaining to residues of lindane in or on cabbage harvested 56-152 days following the last of three applications including: (i) seed treatment with the 40% FLC (GA, only) or 25% WP formulation at 0.031 lb ai/100 lb seed; (ii) a pre-transplanting, broadcast incorporated soil application of the 25% WP formulation at 0.5 lb ai/A; and (iii) two weeks after transplanting, a post-directed soil application of the 25% WP formulation at 0.5 lb ai/A. Residues were <0.005(nondetectable; ND)-0.016 ppm in or on 18 samples. Apparent residues were <0.005(ND) ppm in or on six untreated samples. Data were collected using a GLC/ECD method, with a limit of detection for lindane residue of 0.005 ppm. Recoveries of lindane were 81-118% from three samples fortified with lindane at 0.01-0.51 ppm. Samples were stored frozen at -20 C for 61-103 days prior to analysis.

Geographic representation is adequate since the test states of CA(8%), FL(16%), GA(2%), NY(15%), TX(16%), and WI(9%) accounted for ca. 70% of the U.S. cabbage acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 338). The available data indicate that residues of lindane do not exceed the 1 ppm tolerance when harvested 56-152 days following seed treatment with either the 40% FLC or 25% WP formulations at 0.031 lb ai/100 lb seed, and preplant and posttransplant soil-directed applications with the 25% WP formulation at 0.5 lb ai/A. However, no data were submitted reflecting foliar uses of lindane and insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on cabbage must submit additional data.

Cucurbit Vegetables Group

Cucumber

Tolerance(s):

A tolerance of 3 ppm has been established for the residues of lindane (gamma isomer of benzene hexachloride) in or on cucumbers [40 CFR §180.133].

Use directions and limitations:

The Agency Product Search Listing (SPO5) dated 7/30/90 includes 25% D, 25% EC, 30 and 40% FLC, 4 lb/gal FLC, 35 and 75% WP/D, and 25 and 75% WP formulations registered for seed treatment use on cucumbers, 1.63 lb/gal EC, 10.68 and 20% EC, 25% WP/D, and 6 and 25% WP formulations registered for soil applications to cucumbers, and 20% EC, 10 and 25% WP, 25% WP/D, 1% D, and 5% SLC formulations registered for foliar applications to cucumbers.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting residues of lindane in or on cucumbers following a treatment series including seed treatment, soil, and foliar applications, and, in a separate test, greenhouse fumigation with an Impr formulation. Also required are label amendments specifying a maximum seasonal application rate and a specific PHI for foliar applications. [Note: The 8/11/89 update to the Index does not list product registrations for either greenhouse fumigation on cucumbers; thus, residue data to support this use is no longer required.]

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1989; MRID 41289404) indicating that residues of lindane in or on cucumbers do not exceed the established 3 ppm tolerance when harvested 9-52 days following seed treatment with either the 40% FLC or 25% WP formulations at 0.0625 lb ai/100 lb

seed, and preplant and postplant soil applications with the 25% WP formulation at 0.5 lb ai/A. However, no data were submitted reflecting foliar uses of lindane and insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on cucumbers must submit the following additional data:

- Data depicting lindane residues of concern in or on cucumbers harvested following seed treatment with a representative EC, FLC, WP/D, or WP formulation, soil applications with a representative EC, WP/D, or WP formulation, and foliar application with a representative D, SLC, EC, WP/D, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on cucumbers must be conducted in CA(11%), FL(6%), MI(19%), NJ(1%), NC(15%), TX(8%), and WI(7%) since these states accounted for ca. 67% of the 1988 U.S. cucumber production (Vegetables, 1988 Summary, Ag. Statistics Board, NASS, USDA June 1989, p. 40).

References (used):

MRID(s): 41289404.

Discussion of the data:

Rhône-Poulenc (1989; MRID 41289404) submitted data from seven tests conducted in CA, FL, MI, NC, NY, OH, and TX pertaining to residues of lindane in or on cucumbers harvested 9-52 days following the last of three applications including: (i) seed treatment with the 40% FLC (FL, only) or 25% WP formulation at 0.0625 lb ai/100 lb seed; (ii) a pre-transplanting, broadcast incorporated soil application of the 25% WP formulation at 0.5 lb ai/A; and (iii) prior to cucumber fruit formation, a post-directed soil application of the 25% WP formulation at 0.5 lb ai/A. Residues were <0.005(nondetectable; ND)-0.106 ppm in or on 21 samples. Apparent residues were <0.005(ND)-0.007 ppm in or on seven untreated samples. Data were collected using a GLC/ECD method, with a limit of detection for lindane of 0.005 ppm. Recoveries of lindane were 88-108% from four samples fortified with lindane at 0.0102-1.69 ppm. Samples were stored frozen at -18 to -23 C for 25-163 days prior to analysis.

Geographic representation is adequate since the test states of CA(11%), FL(6%), MI(19%), NC(15%) and neighboring states of SC(6%), NY(<1%), OH(6%), and TX(8%) collectively accounted for ca. 70% of the U.S. cucumber production (Vegetables, 1988 Summary, Ag. Statistics Board, NASS, USDA June 1989, p. 40). The available data indicate that residues of lindane do not exceed the 3 ppm tolerance when harvested 9-52 days following seed treatment with either the 40% FLC or 25% WP formulations at

0.0625 lb ai/100 lb seed, and preplant and posttransplant soil-directed applications with the 25% WP formulation at 0.5 lb ai/A. However, no data were submitted reflecting foliar uses of lindane and insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on cucumbers must submit additional data.

Pome Fruits Group

Apples

Tolerance(s):

A tolerance of 1 ppm has been established for the residues of lindane (gamma isomer of benzene hexachloride) in or on apples [40 CFR §180.133].

Use directions and limitations:

The Agency Product Search Listing (SPO5) dated 7/30/90 includes 1.63 lb/gal EC, 5, 10, 10.68, 12.5, 12.8, and 20% EC, and 25% WP formulations registered for bark applications to apple trees and 25% WP, 25% WP/D, 20 and 40% EC, and 40% FLC formulations registered for foliar applications to apple trees.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting residues of lindane in or on apples following a treatment series including bark and foliar applications, which must include a representative EC formulation. Also required are label amendments specifying a specific PHI and a maximum seasonal application rate (expressed in pounds per 100 gallons (lb/100 gal) and in pounds per acre (lb/A) for foliar applications). Additionally, a label amendment is required for all end-use products specifying a prohibition against grazing livestock on cover crops beneath treated trees. The Guidance Document also requires processing data on apple juice and wet and dry pomace.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data indicating that residues of lindane in or on apples (MRID 41289401) do not exceed the established 1 ppm tolerance when harvested 60-63 days following the last of three bark applications of the 25% WP formulation at 0.005-0.25 lb ai/A. Data from the submitted processing study (MRID 41289402) indicate that minimal (1.2x) residue concentration may occur in dry pomace processed from apples following bark application. However, no data were submitted reflecting foliar uses of lindane, especially use of a representative EC formulation; thus, additional field residue and processing data are required to support this use. Also, insufficient data are available to assess the adequacy of current label directions. Parties

interested in retaining registered uses on apples must submit the following additional data:

- Data depicting lindane residues of concern in or on apples harvested following bark applications with a representative EC or WP formulation and foliar application with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on apples must be conducted in CA(7%), MI(9%), NY(10%), NC(4%), and WA(43%) since these states accounted for ca. 73% of the 1988 U.S. apple production (Agricultural Statistics Board, NASS, USDA, Aug 1989).
- A processing study depicting the potential for concentration of lindane residues of concern in wet and dry pomace, and apple juice from the processing of apples bearing measurable, weathered residues following foliar application. If residues concentrate in any processed product appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on apples.

References (used):

MRID(s): 41289401. 41289402.

Discussion of the data:

Rhône-Poulenc Ag Co. (1989; MRID 41289401) submitted data from six studies conducted in CA, MI, NY, NC, PA, and WA pertaining to residues of lindane in or on apples harvested 60-63 days following the last of three bark applications (using ground equipment) of the 25% WP formulation at 0.0625-0.25 lb ai/100 gal of water. Residues of lindane were <0.005 ppm (nondetectable; ND) in or on 18 apple samples. Apparent residues of lindane were <0.005(ND) ppm in or on six untreated samples. Data were collected using a GLC/ECD method with a limit of detection of 0.005 ppm. Recoveries were 98-118% from three samples fortified with lindane at 0.0102-0.5095 ppm. Samples were stored frozen at -17 to -23 C for ca. 49-76 days prior to analysis.

In a separate submission, Rhône-Poulenc AG Co. (1989; MRID 41289402) submitted data from four tests conducted in CA, MI, NC, and WA pertaining to residues of lindane in or on wet and dry pomace, and apple juice processed from apples harvested 60-63 days following the last of three bark applications of the 25% WP formulation at 0.0625-0.25 lb ai/100 gal of water. Residues of lindane in or on nine samples each of whole apples, wet pomace,

dry pomace, and juice were nondetectable (<0.005 ppm). Residues from one location (CA) were <0.005(ND)-0.008 ppm in or on three samples of whole apples, <0.005(ND)-0.008 ppm in or on three samples of wet pomace (up to 1.2x concentration factor), <0.005(ND)-0.007 ppm in or on three samples of dry pomace, and <0.005 ppm (ND) in or on three samples of juice. Apparent residues were <0.005 ppm (ND) in or on sixteen untreated samples. Data were collected using a GLC/ECD method with a limit of detection of 0.005 ppm. Recoveries were 98-108% from three samples of whole apples, 78-108% from three samples of apple juice, 98-108% from three samples of wet pomace, and 78-124% from three samples of dry pomace fortified with lindane at 0.0051-0.509 ppm. Samples were stored frozen at -17 to -24 C for ca. 65-113 days prior to analysis.

Geographic representation is adequate since the test states of CA (7%), MI(9%), NY(10%), NC(4%), PA(6%), and WA(43%) accounted for ca. 80% of the 1988 U.S. apple production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug 1989). The available field data indicate that residues of lindane in or on apples do not exceed the established 1 ppm tolerance when harvested 60-63 days following the last of three bark applications of the 25% WP formulation at 0.005-0.25 lb ai/A. The available processing data indicate that minimal (1.2x) residue concentration may occur in dry pomace processed from apples following bark application. However, no data were submitted reflecting foliar uses of lindane, especially use of a representative EC formulation; thus, additional field residue and processing data are required to support this use. Also, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on apples must submit additional data.

Stone Fruits Group

Peaches

Tolerance(s):

A tolerance of 1 ppm has been established for the residues of lindane (gamma isomer of benzene hexachloride) in or on peaches [40 CFR §180.133].

Use directions and limitations:

The Agency Product Search Listing (SP05) dated 7/30/90 includes 1.63 lb/gal EC and 5, 10, 12.5, 12.8, and 20% EC formulations registered for bark applications to peach trees and 6% WP and 10.68 and 20% EC formulations registered for foliar applications to peach trees.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting residues of lindane in or on peaches following a treatment series including bark and foliar applications, which must include a representative EC formulation. Also required are label amendments specifying a revised PHI to reflect residue data from several varieties of peaches with different maturation dates and a maximum seasonal application rate (expressed in pounds per 100 gallons (lb/100 gal) and in pounds per acre (lb/A) for foliar application). Additionally, a label amendment is required for all end-use products specifying a prohibition against grazing livestock on cover crops beneath treated trees.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1989; MRID 41289408) indicating that residues of lindane in or on peaches do not exceed the established 1 ppm tolerance following a single bark application of the 25% WP formulation at 0.0625-0.25 lb ai/100 gal of water. However, the 25% WP formulation is not currently registered for use on peaches. In addition, no data were submitted reflecting foliar uses of lindane, especially use of a representative EC formulation. Also, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on peaches must submit the following additional data:

- Data depicting lindane residues of concern in or on peaches harvested following bark applications with a representative EC or WP formulation and foliar application with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on peaches must be conducted in CA(59%), MI(2%), PA(3%) or NJ(3%), SC(13%) or GA(5%), and WA(2%) since these states accounted for ca. 70-80% of the 1988 U.S. peach production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).

References (used):

MRID(s): 41289408.

Discussion of the data:

Rhône-Poulenc AG Co. (1989; MRID 41289408) submitted data from five tests conducted in CA(1), GA(1), MI(1), PA(1), and WA(1) pertaining to residues of lindane in or on peaches harvested 59-70 days following a single bark application of the 25% WP at 0.0625-0.25 lb ai/100 gal of water. Residues were nondetectable (<0.005 ppm) in or on 14 samples. Apparent residues were also nondetectable (<0.005 ppm) in or on five untreated samples. Data were collected using a GLC/ECD method with a limit of detection

for lindane of 0.005 ppm. Recoveries were 97-118% from three samples fortified with lindane at 0.0102-0.51 ppm. Samples were stored frozen at ca. -20 C for 93-200 days prior to analysis.

Geographic representation is adequate since the test states of CA(59%), GA(5%), MI(2%), PA(3%), and WA(2%) accounted for ca. 71% of the 1988 U.S. peach production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989). The available data indicate that residues of lindane in or on peaches do not exceed the established 1 ppm tolerance when harvested 59-70 days following a single bark application of the 25% WP formulation at 0.0625-0.25 lb ai/100 gal of water. However, the 25% WP formulation is not currently registered for use on peaches. In addition, no data were submitted reflecting foliar uses of lindane, especially use of a representative EC formulation. Also, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on peaches must submit additional data.

Small Fruits and Berries Group

Grapes

Tolerance(s):

A tolerance of 1 ppm has been established for the residues of lindane (gamma isomer of benzene hexachloride) in or on grapes [40 CFR §180.133].

Use directions and limitations:

The Agency Product Search Listing (SP05) dated 7/30/90 includes only the 40% EC formulation registered for foliar application to grapes.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting residues of lindane in or on grapes following treatment reflecting foliar applications of an EC formulation at the maximum current use, and revised labeling indicating application rates in terms of pounds of active ingredient per acre, number of total applications per season, and the interval between applications. The Guidance Document also requires a processing study.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1989; MRID 41289405) indicating that residues of lindane in or on grapes do not exceed the established 1 ppm tolerance when harvested 68-89 days following a single foliar application (to the base of the vine) of the 20% EC formulation at 0.22-1.24 lb ai/A. Additionally, Rhône-Poulenc AG Co.

submitted data (1989; MRID 41289406) from processing studies indicating that residues of lindane were detectable in some samples of grape juice and wet and dry pomace, and were nondetectable in all raisin and raisin waste samples, when harvested 68-70 days following a single foliar application (to the base of the vine) of the 20% EC formulation at 0.22-0.62 lb ai/A. However, the 20% EC formulation is not currently registered for use on grapes. Also, the submitted processing studies used grapes bearing nondetectable residues, and insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on grapes must submit the following additional data:

- Data depicting lindane residues of concern in or on grapes harvested following foliar applications with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on grapes must be conducted in CA(92%), NY(3%), and WA(3%) since these states accounted for ca. 98% of the 1988 U.S. grape production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).
- A processing study depicting the potential for concentration of lindane residues of concern in wet and dry pomace, raisins, raisin waste, and grape juice from the processing of grapes bearing measurable, weathered residues. If residues concentrate in any processed product appropriate food/feed additive tolerances must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on grapes.

References (used):

MRID(s): 41289405. 41289406.

Discussion of the data:

Rhône-Poulenc AG Co. (1989; MRID 41289405) submitted data from four studies conducted in CA(1), MI(1), NY(1), and WA(1) pertaining to residues of lindane in or on grapes harvested 68-89 days following a single foliar application (applied to the base of the vine using ground equipment) of the 20% EC formulation at 0.22-1.24 lb ai/A. Residues of lindane were <0.005(nondetectable; ND)-0.016 ppm in or on 12 samples. Apparent residues of lindane were nondetectable (<0.005 ppm) in or on four untreated samples. Data were collected using a GLC/ECD method with a limit of detection of 0.005 ppm.

Recoveries were 104-118% from three samples fortified with lindane at 0.0102-0.561 ppm. Samples were stored frozen at ca. -20 C for 71-80 days prior to analysis.

Rhône-Poulenc AG Co. (1989; MRID 41289406) submitted data from two processing studies conducted in CA(1) and WA(1) pertaining to residues of lindane in or on juice, wet pomace, dry pomace, raisin, and raisin waste processed from grapes bearing nondetectable residues (<0.005 ppm). Grapes (six samples) were harvested 68-70 days following a single foliar application (applied to the base of the vine using ground equipment) of the 20% EC formulation at 0.22-0.62 lb ai/A and processed by simulated commercial procedures. Residues were nondetectable (<0.005 ppm) in or on six samples of juice, three samples of raisins, and three samples of raisin waste. Residues were <0.005(ND)-0.015 ppm (up to 3x concentration) in or on six samples of wet pomace and <0.005(ND)-0.026 ppm (up to 5.2x concentration) in or on six samples of dry pomace. Apparent residues of lindane were <0.005 ppm (ND) in or on 10 untreated samples. Data were collected using a GLC/ECD method with a limit of detection of 0.005 ppm. Recoveries were 77 and 108% from two grape samples, 84 and 118% from two juice samples, 98 and 115% from two wet pomace samples, 100 and 118% from two dry pomace samples, 118% from one raisin sample, and 84% from one raisin waste sample fortified with lindane at 0.0102-0.509 ppm. Samples were stored frozen at ca. -20 C for 92-176 days prior to analysis.

Geographic representation is adequate since the test states of CA (92%), MI(1%), NY(3%), and WA(3%) accounted for ca. 99% of the 1988 U.S. grape production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989). The available data indicate that residues of lindane in or on grapes do not exceed the established 1 ppm tolerance when harvested 68-89 days following a single foliar application (applied to the base of the vine) of the 20% EC formulation at 0.22-1.24. Additionally, processing studies indicate that residues of lindane were detectable in some samples of grape juice and wet and dry pomace, and were nondetectable in all raisin and raisin waste samples when harvested 68-70 days following a single foliar application (applied to the base of the vine) of the 20% EC formulation at 0.22-0.62 lb ai/A. However, the 20% EC formulation is not currently registered for use on grapes. Also, the submitted processing studies used grapes bearing nondetectable residues and insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on grapes must submit additional data.

Tree Nuts Group

Pecans

Tolerance(s):

A tolerance of 0.01 ppm (negligible residue) has been established for the residues of lindane (gamma isomer of benzene hexachloride) in or on pecans [40 CFR §180.133].

Use directions and limitations:

The Agency Product Search Listing (SPO5) dated 7/30/90 includes 1, 1.63, and 1.65 lb/gal EC and 12.5 and 20% EC formulations registered for foliar applications to pecans; the 20% EC formulation is also registered for delayed dormant applications to pecans.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting lindane residues in or on pecans reflecting the maximum registered use of representative formulations. Samples should be ground in an Ultra Centrifugal Mill prior to extraction with a Polytron or Omni-Mixer.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1989 and 1990; MRIDs 41289601 and 41421001) indicating that residues of lindane in or on 11 samples of pecans do not exceed the established 0.01 ppm tolerance when harvested 157-159 days following a single foliar application of the 20% EC formulation at 2.3-3 lb ai/A. However, residues exceeded the 0.01 ppm tolerance in or on one sample harvested 174 days following a single foliar application of the 20% EC at 3 lb ai/A, and in or on one untreated sample. In addition, no data were submitted reflecting delayed dormant uses of lindane, and the submitted data do not represent major areas of pecan production. Also, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on pecans must submit the following additional data:

- Data depicting lindane residues of concern in or on pecans harvested following foliar and delayed dormant applications with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Samples should be ground in an Ultra Centrifugal Mill prior to extraction with a Polytron or Omni-Mixer. Tests on pecans must be conducted in GA(38%), LA(10%), OK(16%), and TX(12%) since these states accounted for ca.

76% of the 1988 U.S. pecan production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).

References (used):

MRID(s): 41289601. 41421001.

Discussion of the data:

Rhône-Poulenc AG Co. (1989 and 1990; MRIDs 41289601 and 41421001, respectively) submitted data from four tests conducted in LA(2), OK(1), and TX(1) pertaining to residues of lindane in or on pecans harvested 157-195 days following a single foliar application of the 20% EC at 2.3-3 lb ai/A. Residues were <0.005(nondetectable; ND)-0.009 ppm in or on 11 samples. One additional sample treated at 3 lb ai/A bore lindane residues of 0.011 ppm. Apparent residues were <0.005(ND)-0.008 ppm in or on three untreated samples and were 0.012 ppm in or on one untreated sample. Data were collected using a GLC/ECD method with a limit of detection for lindane residues of 0.005 ppm. Recoveries were 77-114% from four samples fortified with lindane at 0.006-1.52 ppm. Samples were stored frozen at -5 to -30 C for 2-63 days prior to analysis.

Geographic representation is inadequate since the test states of LA(10%), OK(16%), and TX(12%) and the neighboring states of AR(1%), MS(3%), and NM(9%) collectively accounted for ca. 51% of the 1988 U.S. pecan production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989). The available data indicate that residues of lindane in or on 11 samples of pecans do not exceed the established 0.01 ppm tolerance when harvested 157-159 days following a single foliar application of the 20% EC formulation at 2.3-3 lb ai/A. However, residues exceeded the 0.01 ppm tolerance in or on one sample harvested 174 days following a single foliar application of the 20% EC at 3 lb ai/A and in or on one untreated sample. In addition, the data do not represent major areas of pecan production. Also, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on pecans must submit additional data.

Miscellaneous Commodities

Tobacco

Tolerance(s):

N/A.

Use directions and limitations:

The Agency Product Search Listing (SPO5) dated 7/30/90 includes 10 and 20% EC formulations registered for soil applications (applied in transplanting water) to tobacco transplant beds.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires data depicting residues of lindane in or on tobacco following both foliar and soil (applied to tobacco transplant beds in transplanting water) applications according to the maximum seasonal use pattern (including the total number of foliar applications, and the application interval). If residues of ≥ 0.1 ppm are found in or on green, freshly harvested tobacco, then pyrolysis products derived from the active ingredient must be characterized. [Note: The 8/11/89 update to the Index does not list product registrations for foliar application uses on tobacco; thus, residue data to support these uses are no longer required.]

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1989; MRID 41289409) indicating that residues of lindane do not exceed 0.1 ppm in or on tobacco harvested 70-93 days following an at-transplant soil application to the transplant bed of the 20% EC formulation at 0.0125 lb ai/plant. However, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on tobacco must submit the following additional data:

- Data depicting lindane residues of concern in or on tobacco harvested following soil applications (applied to tobacco transplant beds in transplanting water) with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. If residues of ≥ 0.1 ppm are found in or on green, freshly harvested tobacco, then pyrolysis products derived from the active ingredient must be characterized. Tests on tobacco must be conducted in NC(40%) and KY(26%), since these states and their neighboring states accounted for >70% of the 1988 U.S. tobacco production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).

References (used):

MRID(s): 41289409.

Discussion of the data:

Rhône-Poulenc AG Co. (1989; MRID 41289409) submitted data from two tests conducted in GA and VA pertaining to residues of lindane in or on tobacco leaves harvested 70-93 days after a single transplant application of the 20% EC at 0.0125 lb ai/plant. Residues were <0.005 (nondetectable; ND)-0.090 ppm in or on six samples. Apparent residues were <0.005 (ND) ppm in or on two untreated samples. Data were collected using a GLC/ECD method with a limit of detection for lindane residues of 0.005 ppm. Recoveries were 81 and 118% from two samples fortified with lindane at 0.01-0.51 ppm. Samples were stored frozen at ca. -23 to -28 C for 97-104 days prior to analysis.

Geographic representation is adequate since the test states of GA(6%) and VA(7%) and the neighboring states of KY(26%) and NC(40%) accounted for ca. 80% of the U.S. tobacco production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989). The available data indicate that residues of lindane do not exceed 0.1 ppm in or on tobacco harvested 70-93 days following an at-transplant soil application to the transplant bed of the 20% EC formulation at 0.0125 lb ai/plant. However, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on tobacco must submit additional data.

Crops with Seed Treatments Only

Tolerance(s):

Currently no tolerances exist for crops with seed treatment only. However, these uses have been determined to be food uses, and therefore, tolerances must be proposed in order to maintain registration.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires additional data for the following crops with seed treatments only: alfalfa, barley, beans, beets, carrots, clover, corn, cotton, flax, lentils, oats, radishes, rye, safflower, sorghum, soybeans, sudangrass, sugar beets, sunflowers, and wheat. In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (1987; MRID 40431207) for corn, mustard greens, radishes, spinach, sugar beets, and wheat grown from seeds treated with [¹⁴C]lindane which were reviewed by DEB (EPA Memorandum DEB No. 3259, N. Dodd, dated 3/24/88). DEB has concluded that for lindane, seed treatment reflects a food use requiring tolerances, since residues were detected in plants from treatment of the seeds of leafy vegetables, root crops, and grain crops. Additionally, DEB concluded that characterization of ¹⁴C-residues in samples grown from treated seeds are required in at least one root crop and one grain crop, since residues greater than 1 ppm

were found in root crops and grain crops and this use involves a systemic uptake. However, the nature of the residue in plants is currently not understood. Therefore, the registrant should be urged to complete and submit the required plant metabolism data prior to initiation of required field trials, processing studies, and additional characterization analyses. The following additional data are required:

- The registrant must propose tolerances and submit data for lindane residues of concern in or on sugar beet roots and tops grown from seed treated using a representative D, WP, WP/D, or FlC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in CA(21%), CO(4%), ID(16%), MI(10%), MN(19%), and TX(3%) since these states accounted for ca. 73% of the 1988 sugar beet production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on sugar beets will be translated to data required for beets, carrots, and radishes.
- A processing study depicting the potential for concentration of lindane residues of concern in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on sugar beets.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on peas (succulent and dried), pea vines and pea hay grown from seed treated using a representative D, EC, WP, WP/D, or FlC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in WA(29%) or OR(12%), WI(17%) or MN (17%) and NY(4%) since these states collectively accounted for ca. 80% of the 1988 garden pea production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on soybeans will be translated to dried peas.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on beans (succulent and dried), bean vines and bean hay grown from seed treated using a representative D, EC, WP, WP/D, or FlC formulation. Residue data must reflect use directions and maximum registered application rates specified on

current product labels. The tests must be conducted in WI(32%), OR(22%), and MI(7%) or IL(6%) since these states accounted for ca. 70% of the 1988 snap bean production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on soybeans will be translated to data required for dried beans.

- The registrant must propose tolerances and submit data for lindane residues of concern in or on soybean grain, forage, and hay grown from seed treated using a representative D, EC, WP, WP/D, or FLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in IA(16%), IL(15%), LA(3%) or MS(3%) or AR(5%), NC(2%), and OH(6%), since these states and their bordering states accounted for >85% of the 1988 soybean production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on soybeans will be translated to data required for dried beans and dried peas.
- A processing study depicting the potential for concentration of lindane residues of concern in meal, hulls, soapstock, crude oil, refined oil, and grain dust processed from soybeans bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on soybeans.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on corn grain, forage, and fodder grown from seed treated using a representative D, WP/D, FLC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in IA(18%), IL(14%), NE(17%), OH(5%), and TX(3%) since these states and their bordering states accounted for >80% of the 1988 corn production (Ag. Statistics Board, NASS, USDA Crop Database. Aug. 1989).
- A processing study depicting the potential for concentration of lindane residues of concern in wet milled products (starch, crude oil, and refined oil) and in dry milled products (grits, meal, flour, and crude and refined oils) and grain dust processed from corn bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive

tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on corn grain.

- A processing study depicting the potential for concentration of lindane residues of concern in milled products (flour and starch) and grain dust processed from sorghum bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on sorghum grain.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on wheat grain, forage, hay and straw grown from seed treated using a representative D, EC, WP/D, FlC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in KS(18%), ND(6%), OK(10%), OH(3%), GA(1%) or NC(1%) or SC(1%), and WA(7%) since these states and their bordering states accounted for ca. 80% of the 1988 wheat production (Ag. Statistics Board, NASS, USDA Crop Database. Aug. 1989). Data on wheat will be translated to data required for barley, oats, and rye.
- A processing study depicting the potential for concentration of lindane residues of concern in milled products (bran, flour, middlings, and shorts) and grain dust processed from wheat bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on wheat grain. Data on wheat will be translated to data required for barley, oats, and rye.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on sudangrass grown from seed treated using a representative D, EC, WP/D, FlC, or WP formulation. Residue data must reflect use directions and maximum registered application rates

specified on current product labels. Tests must be conducted in CA and TX.

- The registrant must propose tolerances and submit data for lindane residues of concern in or on alfalfa seed, forage, and hay grown from seed treated using a representative D, EC, WP/D, FlC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA(10%), CO(4%), IA(8%), ID(5%), and PA(4%) since these states and their bordering states accounted for ca. 70% of the 1988 alfalfa production (Ag. Statistics Board, NASS, USDA, Crop Database, Aug. 1989). Data for alfalfa will be translated to data required for clover.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on cottonseed grown from seed treated using a representative D, WP/D, FlC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in AR(7%), CA(18%), MS(12%), and TX(34%) since these states accounted for ca. 70% of the 1988 cotton production (Ag. Statistics Board, NASS, USDA Crop Database, Jan. 1989).
- A processing study depicting the potential for concentration of lindane residues of concern in meal, hulls, soapstock, crude oil, and refined oil processed from cottonseed bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on cottonseed.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on flax seed grown from seed treated using a representative D, FlC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in ND(80%) and SD(13%), since these states accounted for ca. 93% of the 1988 flax production (Ag. Statistics Board, NASS, USDA Crop Database, Jan. 1989).
- A processing study depicting the potential for concentration of lindane residues of concern in meal (linseed) processed from flax seed bearing measurable,

weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on flax seed.

- The registrant must propose tolerances and submit data for lindane residues of concern in or on sunflower seed grown from seed treated using a representative D, WP/D, FlC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in ND(82%) and TX(2%) since these states accounted for ca. 85% of the 1988 sunflower production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989).
- A processing study depicting the potential for concentration of lindane residues of concern in meal, hulls, crude oil, and refined oil processed from sunflower seeds bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on sunflower seeds.
- The registrant must propose tolerances and submit data for lindane residues of concern in or on safflower seed grown from seed treated using a representative D, WP/D, FlC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA(76%) and MT(17%) since these states accounted for ca. 93% of the 1982 safflower production (1982 Census of Agriculture, Vol. 1, Part 51, p. 317).
- A processing study depicting the potential for concentration of lindane residues of concern in meal, crude oil, and refined oil processed from safflower seeds bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on safflower seeds.

References (used):

MRID(s): 40431207.

Discussion of the data:

N/A.

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

Milk and Meat, Fat, and By-products of Cattle, Goats, Hogs, Horses, and Sheep

Tolerance(s):

Tolerances of 7 ppm have been established for the residues of lindane (gamma isomer of benzene hexachloride) in the fat of meat from cattle, goats, horses, and sheep. A tolerance of 4 ppm has been established for residues of lindane in the fat of meat from hogs [40 CFR §180.133].

No tolerance has been established for residues of lindane in milk.

Use directions and limitations:

The Agency Product Search Listing (SPO5) dated 7/30/90 includes 1, 10, 10.68, 11.34, 12.5, 12.8, and 20% EC, 1% D, 1 and 25% WP/D, 1, 6, and 25% WP, 40% FlC, and 3% PrL formulations variously registered for dermal use on cattle, goats, hogs, horses, and sheep.

Conclusions:

The Lindane Guidance Document dated September, 1985 requires additional data for residues of lindane in the fat of cattle, hogs, unshorn lambs, and sheep resulting from the application of sprays, dips, sponge treatment, dusts, backrubbers, and rubbing posts. In addition, the Guidance Document requires revised labels specifying the number of applications and the intervals between applications reflecting the use of sprays and dips, pressurized sprays, and sponge treatments. Data reflecting pre-slaughter intervals are also required.

The Lindane Guidance Document dated September, 1985 also requires a tolerance for lindane residues in milk unless revised labeling bearing restrictions against any method of application to lactating dairy animals (cattle and goats) are submitted.

In response to the Guidance Document, product labels have been revised to restrict uses on dairy animals. Rhône-Poulenc AG Co.

submitted data pertaining to residues of lindane in dairy cattle (MRID 40660505), which was reviewed by DEB (EPA Memorandum DEB No. 4037, M.F. Kovacs, dated 9/20/88) who concluded that the available data do not support the tolerance of 7 ppm for residues in the fat of dairy cattle. DEB also concludes that the data indicate the need for lindane tolerances in the meat, meat byproducts (kidney, heart, and liver), and milk of dairy cattle.

Rhône-Poulenc AG Co. also submitted data pertaining to residues of lindane in sheep (MRID 40660503), which was reviewed by DEB (EPA Memorandum DEB No. 4036, M.F. Kovacs, dated 8/31/88) who concluded that the available data do not support the tolerance of 7 ppm for residues of lindane in the fat of sheep. The data also indicates a need for tolerances in the meat and meat byproducts of sheep.

In addition, Rhône-Poulenc AG Co. submitted data pertaining to residues of lindane in swine (MRID 40660504) which was reviewed by DEB (EPA Memorandum DEB No. 4038, S.H. Willett, dated 8/29/88) who concluded that the available data do not support the tolerance of 4 ppm in hog fat because the data were collected by questionable or unspecified method and the studies did not specify the conditions or duration under which the samples were stored. DEB recommended that the registrant reanalyzed the reserved samples (supportable by storage stability data) and/or conduct a new swine feeding study to quantify any lindane metabolites found to be of toxicological concern. Appropriate tolerances for lindane residues in animal products will need to be established when the nature of the residue has been adequately delineated.

DEB has also concluded that the current product labels for spray and dip treatments impose no limit to the number of applications which can be made to cattle and sheep. A revised label is required which specifies the number of applications permitted and the interval between applications to cattle and sheep. The treatment rate should also be supported by adequate residue data.

The nature of the residue in plants and animals is not understood and data requirements for numerous feed commodities are outstanding. Upon receipt of the requested plant and animal metabolism data and crop residue data: (i) the adequacy of tolerances for residues in animal products will be determined, with consideration of any newly found metabolite of toxicological concern; (ii) the expected dietary intake for beef cattle, dairy cattle, and swine will be calculated; and (iii) the need for additional feeding and dermal treatment studies will be reevaluated.

References (used):

MRID(s): 40660504. 40660503. 40660505.

Discussion of the data:

N/A.

Eggs and the Fat, Meat, and Meat Byproducts of Poultry

Tolerance(s):

No tolerances have been established for residues of lindane in poultry or eggs.

Conclusions:

The Lindane Guidance Document dated September, 1985 concludes that it may be necessary to establish tolerances for residues of lindane in eggs, and the fat, meat, and meat byproducts of poultry if significant levels of lindane are found in poultry feed items. In addition, labeling of all lindane end-use products with directions for use on livestock premises or farm buildings must bear a prohibition against application in poultry houses.

In response to the Guidance Document, Rhône-Poulenc AG Co. submitted data (MRID 40660501) pertaining to the residue of lindane in poultry and eggs which have been reviewed by DEB (EPA Memorandum DEB No. 4034, G.F. Otakie, dated 8/31/88) who concluded that the available data indicate residues accumulate in poultry tissues and eggs. New tolerances for residues of lindane in poultry fat, meat, meat byproducts, and eggs may be required pending results of outstanding plant and poultry metabolism and field crop residue studies. Analysis of reserve samples and/or a new poultry feeding study may be required if any metabolites are of toxicological concern.

Presently, the nature of the residue in plants and animals is not understood and data requirements for numerous feed commodities are outstanding. Upon receipt of the requested plant and animal metabolism and crop residue data: i) tolerances for residues in eggs, and the fat, meat, and meat byproducts of poultry must be established with consideration of all metabolites of toxicological concern; ii) the expected dietary intake for poultry will be calculated; and iii) the need for additional feeding studies will be evaluated.

References (used):

MRID(s): 40660501.

Discussion of the data:

N/A.

MASTER RECORD IDENTIFICATION NUMBERS

MRID documents containing data which have been reviewed by the Agency are designated in shaded blocks in the following bibliographic listing of Residue Chemistry Citations (used). A summary of the memoranda and their associated MRID documents is presented below.

AGENCY MEMORANDA

DEB No. 3267
Subject: Partial Response (November 10, 1987) by Centre International d'Etudes du Lindane (CIEL) to Data Gap 171-4 (Nature of the Residue in Plants as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard)
From: G. Otakie
To: A. Rispin, G. LaRocca, E. Budd
Dated: 3/24/88
MRID(s): 40410902, 40431204. 40431201

DEB No. 3312
Subject: Partial Response (July 21, 1987) by Centre International d'Etudes du Lindane (CIEL) to Data Gap 171-4 (Nature of the Residue in Livestock Ruminants) as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard)
From: C. Deyrup
To: A. Rispin, G. LaRocca, E. Budd
Dated: 3/24/88
MRID(s): 40271302

DEB No. 3315
Subject: Partial Response (July 15, 1987) by Centre International d'Etudes du Lindane (CIEL) to Data Gap 171-4 (Nature of the Residue in Livestock Poultry) as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard)
From: J. Onley
To: A. Rispin, G. LaRocca, E. Budd
Dated: 3/24/88
MRID(s): 40271301

DEB No. 3257
Subject: Lindane Registration Standard Followup - Analytical
Methods for Plants
From: N. Dodd
To: A. Rispin, G. LaRocca, E. Budd
Dated: 3/24/88
MRID(s): 40431202. 40431206

DEB No. 3261
Subject: Lindane Registration Standard Followup - Analytical
Methods for Animal Tissues, Eggs, and Milk
From: N. Dodd
To: A. Rispin, G. LaRocca, E. Budd
Dated: 3/24/88
MRID(s): 40431208

DEB No. 3260
Subject: Lindane Registration Standard Followup - Storage
Stability
From: N. Dodd
To: A. Rispin, G. LaRocca, E. Budd
Dated: 3/24/88
MRID(s): 40431203, 40431205

DEB No. 4035
Subject: Lindane Registration Standard Followup - Storage
Stability Data
From: S. Willett
To: R. Engler, G. LaRocca, E. Budd
Dated: 8/23/88
MRID(s): 40660502

DEB No. 3259
Subject: Lindane Registration Standard Followup - Residues
From Seed Treatment
From: N. Dodd
To: A. Rispin, G. LaRocca, E. Budd
Dated: 3/24/88
MRID(s): 40431207

DEB No. 4037
Subject: Partial Response (December 15, 1987) by Centre
International d'Etudes du Lindane (CIEL) to Data Gap
171-4 [Magnitude of Residue in Animals (Dairy Cattle
Meat and Milk)] as Identified in the Residue
Chemistry Chapter of the September 30, 1985 Lindane
Registration Standard

From: M. Kovacs
To: R. Engler, G. LaRocca, E. Budd
Dated: 9/20/88
MRID(s): 40660505

DEB No.: 4036
Subject: Partial Response (April 7, 1988) by Centre International d'Etudes du Lindane (CIEL) to Data Gap Section 171-4 [Magnitude of Residue in Animals (Sheep)] as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard

From: M. Kovacs
To: R. Engler, G. LaRocca, E. Budd
Dated: 8/31/88
MRID(s): 40660503

DEB No. 4038
Subject: Lindane Registration Standard Followup - Residues in Swine
From: S. Willett
To: R. Engler, G. LaRocca, E. Budd
Dated: 8/29/88
MRID(s): 40660504

DEB No. 4034
Subject: Partial Response (June 9, 1988) by Centre International d'Etudes du Lindane (CIEL) to Data Gap Section 171-4 (Magnitude of the Residue in Poultry and Eggs) as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard
From: G. Otakie
To: R. Engler, G. LaRocca, E. Budd
Dated: 8/31/88
MRID(s): 40660501

The following references were obtained from a Guideline Sequence Number search conducted on 9/27/90 for documents on lindane.

Residue Chemistry Citations (used):

40271301 Merricks, D. (1987) Determining the Metabolic Fate of Radiolabeled Lindane Fed to Laying Hens: Laboratory Project No. 1503. Unpublished compilation prepared by Agrisearch Inc. 47 p.

40271302 Wilkes, L.; Mulkey, N.; Hallenbeck, S.; et al. (1987) Metabolism Study of Carbon 14:-Lindane Fed of Topically Applied to Lactating Goats: Laboratory Project No. ADC 957. Unpublished study prepared by Analytical Development Corp., in cooperation with Rhone-Poulenc Inc. 304 p.

40410902 Gemma, A. (1987) Metabolism of Carbon 14:-Lindane in/on Apple Leaves and Fruit after Treatment with Carbon 14:-Lindane 25% EC: Project No.: 799R14: File No.: 40152. Unpublished study prepared by Rhone-Poulenc Inc. 89 p.

40431201 England, D. (1987) Insecticides: Lindane: Metabolism in Spinach Plants Following Post-emergence Application: Laboratory Project ID: D. Ag. 571. Unpublished study prepared by May & Baker Ltd. 62 p.

40431202 Godward, P. (1987) Insecticides: Lindane: Analytical Procedure for the Determination of Residues in Spinach: Laboratory Project ID: D. Ag. 573. Unpublished study prepared by May & Baker Ltd. 41 p.

40431203 Godward, P. (1987) Insecticides: Lindane: Storage Stability Study on Fortified Spinach Samples: Laboratory Project ID: D. Ag. 572. Unpublished study prepared by May & Baker Ltd. 20 p.

40431204 England, D. (1987) Insecticides: Lindane: Metabolism in Cucumber Plants Following Post-emergency Application: Laboratory Project ID: D. Ag. 570. Unpublished study prepared by May & Baker Ltd. 96 p.

40431205 England, P. (1987) Insecticides: Lindane: Storage Stability Study on Fortified Cucumber Samples: Laboratory Project ID: D. Ag. 569. Unpublished study prepared by May & Baker Ltd. 20 p.

40431206 Godward, P. (1987) Insecticides: Lindane: Analytical Procedure for the Determination of Residues in Cucumbers: Laboratory Project ID: D. Ag. 568. Unpublished study prepared by May & Baker Ltd. 41 p.

40431207 Pisanik, M. (1987) The Uptake and Translocation of Radioactive Residues in Plants Grown from Seeds Treated with a Carbon 14: Radiolabelled Lindane Emulsifiable Concentrate (EC) Formulation: ASD No. 87/243. Unpublished study prepared by Rhone-Poulenc Inc. 107 p.

40431208 Pisanik, M. (1987) An Analytical Method for the Determination of Lindane in Animal Tissues, Eggs and Milk: Laboratory Project ID: ASD No. 87/241. Unpublished study prepared by Rhone-Poulenc Inc. 36 p.

40660501 Merricks, D. (1988) Lindane Tissue and Egg Residue Study in Poultry: Final Report: Agrisearch Project No. 1507. Unpublished study prepared by Agrisearch, Inc. 96 p.

40660502 Plisnik, M.; Ziegelbein, J.; Margitics, I.; et al. (1988) Freezer Storage Stability of Lindane in Animal Tissues, Eggs, and Milk: Project No. 799R14. Unpublished study prepared by Rhone-Poulenc Ag Co. 38 p.

40660503 Billings, T. (1988) Tissue Residue Study in Sheep Using Lindane: Laboratory Project No. 87050. Unpublished study prepared by Southwest Bio-Labs, Inc. 285 p.

40660504 Billings, T. (1988) Tissue Residue Study in Swine Using Lindane: Laboratory Project No. 87048. Unpublished study prepared by Southwest Bio-Labs, Inc. 259 p.

40660505 Merricks, D. (1987) Lindane Tissue and Milk Residue Study in Dairy Cows: Agrisearch Project NO. 1508. Unpublished study prepared by Agrisearch, Inc. 117 p.

41289401 Landis Associates, Inc. (1988) Lindane 25% WP: Raw Agricultural Commodity Field Residue Protocol on Apples in California, Michigan, New York, Pennsylvania, North Carolina, and Washington: Lab Project Number: HLA/6237/116A. Unpublished study prepared by Hazleton Laboratories America, Inc. 386 p.

41289402 Landis Associates, Inc. (1989) Lindane 25% WP: Processed Commodity Field Residue Protocol on Apples in California, Michigan, North Carolina, and Washington: Lab Project Number: HLA/6237/116PA. Unpublished study prepared by Hazleton Laboratories, America. 588 p.

41289403 Landis Associates, Inc. (1989) Lindane 25% WP & 40% F: Raw Agricultural Commodity Field Residue Protocol on Cabbage in California, New York, Florida, Georgia, Texas, and Wisconsin: Lab Project Number: HLA/6237/116CA. 417 p.

41289404 Landis Associates, Inc. (1989) Lindane 25% WP & Lindane 40% F: Raw Agricultural Commodity Field Residue Protocol on Cucumbers in California, Ohio, and Michigan: Lab Project Number: HLA/6237/116CU. Unpublished study prepared by Hazleton Laboratories, America 438 p.

41289405 Landis Associates, Inc. (1988) Lindane 20% EC: Raw Agricultural Commodity Field Residue Protocol on Grapes in California, Michigan, New York, and Washington: Lab Project Number: HLA/6237/116G. Unpublished study prepared by Hazleton Laboratories America, Inc. 333 p.

41289406 Landis Associates, Inc. (1988) Lindane 20% EC: Processed Commodity Field Residue Protocol on Grapes in California, New York, and Washington: Lab Project Number: HLA/6237/116PG. Unpublished study prepared by Hazleton Laboratories America, Inc. 367 p.

41289407 Landis Associates, Inc. (1989) Lindane 25% WP and 40% F: Raw Agricultural Commodity Field Residue Protocol on Lettuce in California, Texas, New York, and New Jersey: Lab Project Number HLA/6237/116L. Unpublished study prepared by Hazleton Laboratories America, Inc. 471 p.

41289408 Landis Associates, Inc. (1989) Lindane 25% WP: Raw Agricultural Commodity Field Residue Protocol on Peaches in California, Michigan, Washington, Pennsylvania, and Georgia: Lab Project Number: HLA/6237/116P. Unpublished study prepared by Hazleton Laboratories America, Inc. 345 p.

41289409 Landis Associates, Inc. (1989) Lindane 20% EC: Raw Agricultural commodity field residue protocol on tobacco in Virginia and Georgia: Lab. Project_number: HLA/6237/116p. unpublished study prepared by Hazleton Laboratories America, Inc. 237 p.

41289601 Landis Associates, Inc. (1989) Lindane 20% EC: Raw Agricultural Commodity Field Residue Protocol on Pecans in Louisiana, Texas, and Oklahoma: Lab Project Number: 6237/116. Unpublished study prepared by Hazleton Laboratories America, Inc. 257 p.

41421001 Walker, K. (1990) Lindane 20 [Percent! EC: Raw Agricultural Commodity Field Residue Protocol on Pecans in Louisiana: Lab Project Number: 6237-116 PC. Unpublished study prepared by Hazleton Laboratories America, Inc. 153 p.

Residue Chemistry Citations (not used):

[The following MRIDs contain data that were either not submitted in response to the Guidance Document or contain data that are not useful in satisfying residue chemistry data requirements.]

00153988 Fuhremann, T.; Lichtenstein, E. (1980) A comparative study of the persistence, movement, and metabolism of six carbon-14 insecticides in soil plants. Journal of Agri. Food Chem. 28(2):446-452.

00160330 Jain, P.; Gupta, H. (1976) Persistence of lindane, malathion and parathion residues on brinjal fruits. Annals of Arid Zone 15 (1/2):37-42.

00160342 Varis, A. (1972) Loss of lindane, dimethoate, and methyl parathion residues from seedlings of sugar beet as influenced by plant growth. An. Ag. Fenniae 11:381-385.

00163460 Oehler, D.; Hogan, B.; Graham, O. (1970) Residues in milk following treatment of cows with lindane or ronnel to control screw-worms. Journal of Economic Entomology 63(5):1467-1468.

00164641 Yeh, S. (1986) Eighteen-month Mancozeb Storage Stability Study on Grapes: Technical Report No. 310-86-53. Unpublished study prepared by Rohm & Haas Co., Spring House Research Laboratories. 14 p.

40145901 Merricks, L. (1987) Lindane: Aquatic Residue Monitoring Study: Final Report Addendum: Laboratory Project ID. 1502. Unpublished study prepared by Agrisearch Inc. 104 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR LINDANE.

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)?
<u>40 CFR §158.240 Residue Chemistry</u>				
171-2. Chemical Identity ³				
171-3. Directions for Use				
		(See Index) ⁴		
171-4. Nature of the Residue (Metabolism)	PAIRA	Partially	40410902 40431204 40431201	Yes ⁵
- Plants				
171-4. Nature of the Residue (Metabolism)	PAIRA & plant metabolites	Partially	40271301 40271302	Yes ^{6,7}
- Livestock				
171-4. Residue Analytical Methods	TGAI & metabolites	Partially	40431202 40431206 40431208	Yes ⁸
171-4. Storage Stability	TEP & metabolites	Partially	40431203 40431205 40660502	Yes ^{9,10}
171-4. Magnitude of Residue in Plants ¹¹				
<u>Root and Tuber Vegetables</u>				
- Beets, garden (seed treatment)	TEP	Partially		Yes ¹²
- Carrots (seed treatment)	TEP	Partially		Yes ¹³

(Continued, footnotes follow)

SA

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)?
- Sugar beets (seed treatment)	TEP	Partially		Yes ¹⁴
(processed commodities)	TEP	No		Yes ¹⁵
- Radishes (seed treatment)	TEP	Partially		Yes ¹⁶
<u>Leaves of Root and Tuber Vegetables</u>				
- Beets, garden tops (seed treatment)	TEP	Partially		Yes ¹⁷
- Sugar beet tops (seed treatment)	TEP	Partially		Yes ¹⁸
- Radish tops (seed treatment)	TEP	Partially		Yes ¹⁹
<u>Bulb Vegetables</u>				
- Onions (dry bulb)	TEP	No		Yes ²⁰
<u>Leafy Vegetables (except Brassica)</u>				
- Celery	TEP	No		Yes ²¹
- Lettuce	TEP	Partially	41289407	Yes ²²
- Spinach	TEP	No		Yes ²³

(Continued, footnotes follow)

A

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)?
<u>Brassica Leafy Vegetables</u>				
- Broccoli	TEP	No		Yes ²⁴
- Brussels sprouts	TEP	No		Yes ²⁵
- Cabbage	TEP	Partially	41289403	Yes ²⁶
- Cauliflower	TEP	No		Yes ²⁷
- Collards	TEP	No		Yes ²⁸
- Kale	TEP	No		Yes ²⁹
<u>Legume Vegetables and Foliage of Legume Vegetables</u>				
- Beans (succulent & dried) (seed treatment)	TEP	Partially		Yes ³⁰
- Peas (succulent & dried) (seed treatment)	TEP	Partially		Yes ³¹
- Soybeans (seed treatment)	TEP	Partially		Yes ³²
(processed commodities)	TEP	No		Yes ³³
<u>Fruiting Vegetables (except cucurbits)</u>				
- Eggplant	TEP	No		Yes ³⁴

(Continued, footnotes follow)

22

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)?
- Peppers	TEP	No		Yes ³⁵
- Tomatoes (processed commodities)	TEP	No		Yes ³⁶
	TEP	No		Yes ³⁷
<u>Cucurbit Vegetables</u>				
- Cucumbers	TEP	Partially	<u>41289404</u>	Yes ³⁸
- Melons	TEP	No		Yes ³⁹
- Pumpkins	TEP	No		Yes ⁴⁰
- Squash	TEP	No		Yes ⁴¹
<u>Pome Fruits</u>				
- Apples (processed commodities)	TEP	Partially	<u>41289401</u>	Yes ⁴²
	TEP	Partially	<u>41289402</u>	Yes ⁴³
- Pears	TEP	No		Yes ⁴⁴
<u>Stone Fruits</u>				
- Apricots	TEP	No		Yes ⁴⁵
- Cherries	TEP	No		Yes ⁴⁶
- Peaches	TEP	Partially	<u>41289408</u>	Yes ⁴⁷

(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)?
- Plums (fresh prunes) (processed commodities)	TEP	No		Yes ⁴⁸
	TEP	No		Yes ⁴⁹
<u>Small Fruits & Berries</u>				
- Grapes (processed commodities)	TEP	Partially	41289405	Yes ⁵⁰
	TEP	Partially	41289406	Yes ⁵¹
- Strawberries	TEP	No		Yes ⁵²
<u>Tree Nuts</u>				
- Pecans	TEP	Partially	41289601 41421001	Yes ⁵³
<u>Cereal Grains and Forage, Fodder, and Straw</u>				
- Barley (seed treatment) (processed commodities)	TEP	Partially		Yes ⁵⁴
	TEP	No		Yes ⁵⁵
- Corn (field, sweet, and pop) (seed treatment) (processed commodities)	TEP	Partially		Yes ⁵⁶
	TEP	No		Yes ⁵⁷
- Oats (seed treatment) (processed commodities)	TEP	Partially		Yes ⁵⁸
	TEP	No		Yes ⁵⁹
- Rye (seed treatment) (processed commodities)	TEP	Partially		Yes ⁶⁰
	TEP	No		Yes ⁶¹

(Continued, footnotes follow)

84

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)?
- Sorghum (seed treatment) (processed commodities)	TEP	Partially		Yes ⁶²
- Wheat (seed treatment) (processed commodities)	TEP	No		Yes ⁶³
	TEP	Partially		Yes ⁶⁴
	TEP	No		Yes ⁶⁵
<u>Grass Forage, Fodder, and Hay</u>				
- Sudangrass (seed treatment)	TEP	Partially		Yes ⁶⁶
<u>Non-Grass Animals Feeds</u>				
- Alfalfa forage and hay (seed treatment)	TEP	Partially		Yes ⁶⁷
- Clover forage and hay (seed treatment)	TEP	Partially		Yes ⁶⁸
<u>Miscellaneous Commodities</u>				
- Cottonseed (seed treatment) (processed commodities)	TEP	Partially		Yes ⁶⁹
	TEP	No		Yes ⁷⁰
- Flax (seed treatment) (processed commodities)	TEP	Partially		Yes ⁷¹
	TEP	No		Yes ⁷²

(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)?
- Okra	TEP	No		Yes ⁷³
- Safflower seeds (seed treatment) (processed commodities)	TEP	Partially		Yes ⁷⁴
- Sunflower seeds (seed treatment) (processed commodities)	TEP	No		Yes ⁷⁵
- Sunflower seeds (seed treatment) (processed commodities)	TEP	Partially		Yes ⁷⁶
- Tobacco	TEP	No		Yes ⁷⁷
	PAIRA	Partially	41289409	Yes ⁷⁸
171-4. Magnitude of residue in TCAL or plant		Partially		Reserved ⁷⁹
- Meat/Milk/Poultry/Eggs metabolites				

1. Test substance: PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = Typical end-use product; TCAL = technical grade of the active ingredient; MP = manufacturing-use product.
2. These references were submitted in response to the Lindane Guidance Document dated 9/85. Underlining indicates documents that have been reviewed for 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 8/11/89 update of the index of uses for Lindane and the Agency Product Search Listing (SP05) dated 7/30/90 was used to create this document.

16.

TABLE A. (Continued).

5. The plant metabolism data submitted in response to the Guidance Document do not satisfy the requirements for this topic because only ca. 25% of the TRR in apples was adequately identified and 90 and 99% of the applied radioactivity in the studies with cucumbers and spinach was lost. The following additional data are required: Additional data are required to verify the results reported in the submitted metabolism studies on apples, cucumbers, and spinach (MRIDs 40410902, 40431204, and 40431201): (i) total radioactive residues before and after extraction and of the remaining solid residue subjected to combustion; (ii) storage intervals and conditions of frozen storage including the period before frozen storage, extraction, clean up and analysis; (iii) confirmation of the level of lindane and any metabolite identified by TLC using GLC/MS; (iv) an explanation of the significant variation in the total ^{14}C -residues found in mature apples from combustion/LSS compared to extraction/LSS; (v) an alternative procedure for concentrating the samples to dryness in order to prevent possible volatilization of metabolites; and (vi) legible copies of spray test calibrations, HPLC chromatograms, and GLC-MS results. 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. New radiolabeled metabolism studies conducted at exaggerated rates and including acidic, basic and enzymatic hydrolysis to release conjugated residues may be necessary to adequately characterize metabolites. If metabolism data differ significantly among these crops, then metabolism data will be required for a representative crop from each crop grouping for which there is a registered tolerance.

6. The ruminant metabolism data submitted in response to the Guidance Document do not satisfy the requirements for this topic because only 4.5-7.0% of the TRR in kidney and 0.3-0.7% in liver was identified, and the ten metabolites identified in goat tissues and milk must be confirmed by GLC/MS. The following additional data are required: For the metabolism study in lactating goats reflecting oral and topical application (MRID 40271302): (i) data depicting a more complete characterization of the TRR in the liver and kidney of ruminants; (ii) additional information to verify the dosages used in the oral goat metabolism study; (iii) data concerning the raw radiometric data for all the various fractions, zones corresponding to identified metabolites, and matrix samples; (iv) confirmation of the identities of the residues by GLC/MS; (v) explanation of the inconsistencies in some of the reported residue levels; (vi) additional chromatograms and recovery data for the expected metabolites from additional goat matrices; and (vii) a Kuderna-Danish concentrator should be used during the concentration step instead of a rotary evaporator.

7. The poultry metabolism data submitted in response to the Guidance Document do not satisfy the requirements for this topic because raw data/calculations, GLC chromatograms, and confirmation of the terminal residues by GLC/MS were not provided. The following additional data are required: For the poultry metabolism study (MRID 40271301): (i) data concerning raw data/calculations, GLC chromatograms, and

91

26

TABLE A. (Continued).

confirmation of terminal residues by GLC/MS; (ii) since lindane residues did not plateau in egg yolk after 4 and 6 days of dosing, a combination long-term [^{14}C]lindane metabolism/feeding study is needed after determination of residues of toxicological concern; and (iii) a Kuderma-Danish concentrator should be used during the concentration step instead of a rotary evaporator.

8. The qualitative nature of the residue in plants and animals has not been adequately described; therefore, the adequacy of the available methods cannot be ascertained. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting additional analytical methods will be required. If radiolabeled validation of existing analytical methodology for plants and animals (refer to "Qualitative Nature of the Residue in Plants" and "Qualitative Nature of the Residue in Animals" for additional details) indicates a major portion of the total radioactive residue is not recovered and identified by these methods, radiolabeled validation of new proposed analytical methodology will be required.

9. The storage stability data submitted in response to the Guidance Document do not fully satisfy the requirements for this topic. DEB has concluded that storage stability data for lindane on cucumbers and spinach are adequate for storage up to 8 months. However, no data were submitted for a tree fruit (pome or stone). In addition, DEB has concluded that lindane is stable in animal tissues, eggs, and milk stored at 18 C for 9 months. The following additional data are required: The sample storage intervals and conditions must be supplied for all residue data submitted in support of tolerances, whether previously submitted or required in this update. Storage stability studies in support of previously submitted residue data must reflect the actual storage conditions and intervals for samples used to generate the residue data. If residue depletion occurs, data will be required which depict the decline in levels of lindane residues of concern in commodities stored under the range of conditions and for the range of intervals specified. Tree fruit samples (pome or stone) bearing measurable, weathered residues or fortified with lindane residues of concern, and fortified meat or milk samples must be analyzed immediately after harvest or fortification and again after storage intervals that allow for reasonable unforeseen 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 on Validity of Pesticide Residue Data available from NTIS under order no. PB 88112362/AS.

10. The nature of the residue in plants and animals is not adequately understood. If the requested data on

50

92

TABLE A. (Continued).

plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting the stability of those residues during storage will be required.

11. NOTE TO SRRD: Since issuance of the 9/85 Lindane Guidance Document registered uses of lindane on asparagus, avocados, guavas, kohlrabi, mangos, mushrooms, mustard greens, nectarines, pineapples, quinces, and Swiss chard have been cancelled. Unless an interested party declares intent to include any of these use sites on a product label and to submit appropriate, supporting residue data, we recommend that these existing tolerances for lindane residues in or on these food/feed commodities be revoked.

12. No data concerning garden beets (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose a tolerance and submit appropriate supporting residue data depicting lindane residues of concern in or on garden beets following seed treatment. Residue data requested for sugar beets will be translated to satisfy the requirements for garden beets.

13. No data concerning carrots (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose a tolerance and submit appropriate supporting residue data depicting lindane residues of concern in or on carrots following seed treatment. Residue data requested for sugar beets will be translated to satisfy the requirements for carrots.

14. No data on sugar beets (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on sugar beet roots and tops grown from seed treated using a representative D, WP, WP/D, or FLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in CA(21%), CO(4%), ID(16%), MI(10%), MN(19%), and TX(3%) since these states accounted for ca. 73% of the 1988 sugar beet production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on sugar beets will be translated to data required for beets, carrots, and radishes.

15. A processing study depicting the potential for concentration of lindane residues of concern in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by

TABLE A. (Continued).

the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on sugar beets.

16. No data concerning radishes (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose a tolerance and submit appropriate supporting residue data depicting lindane residues of concern in or on radishes following seed treatment. Residue data requested for sugar beets will be translated to satisfy the requirements for radishes.

17. No data concerning garden beet tops (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose a tolerance and submit appropriate supporting residue data depicting lindane residues of concern in or on garden beet tops following seed treatment. Residue data requested for sugar beet tops will be translated to satisfy the requirements for garden beet tops.

18. No data on sugar beet tops (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on sugar beet roots and tops grown from seed treated using a representative D, WP, WP/D, or FLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in CA(21%), CO(4%), ID(16%), MI(10%), MN(19%), and TX(3%) since these states accounted for ca. 73% of the 1988 sugar beet production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on sugar beets will be translated to data required for garden beet tops and radish tops.

19. No data concerning radish tops (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose a tolerance and submit appropriate supporting residue data depicting lindane residues of concern in or on radish tops following seed treatment. Residue data requested for sugar beet tops will be translated to satisfy the requirements for radish tops.

20. No data were submitted on onions (dry bulb only) in response to the Guidance Document. The following data remain outstanding: Data depicting lindane residues of concern in or on onions (dry bulb only) harvested following soil and foliar applications with representative D, WP/D, WP, EC, or FLC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues

TABLE A. (Continued).

would be expected to be higher from that type of formulation. A pre-harvest interval (PHI) supported by adequate residue data must appear on all labels with this crop site. The data must be developed from field trials in NY, MI, OR or WA, ID, and CO.

21. No data were submitted on celery in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on celery harvested following soil and foliar applications with representative D, WP/D, WP, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. The residue data should reflect analyses on both trimmed and untrimmed samples, as untrimmed celery may enter interstate commerce. Only obviously decomposed outer leaves or petioles should be removed. A definite pre-harvest interval (PHI) in terms of days, supported by adequate residue data, must appear on all lindane labels with the celery use, rather than the current vague restriction against applying after it is half grown or has begun to bunch. Revised labeling must be submitted that specify the number of applications permitted per season and the time period between these applications. The data must be developed from field trials in CA, FL, MI, and WA.

22. Data on lindane residue in or on lettuce submitted in response to the Guidance Document do not satisfy requirements for this topic because insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on lettuce must submit the following additional data: Data depicting lindane residues of concern in or on lettuce harvested following seed treatment with a representative EC, FLC, or WP formulation and soil applications with a representative EC or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on lettuce must be conducted in CA(73%), CO(1%), FL(3%), NJ(1%), and TX(1%) since these states accounted for ca. 79% of the 1988 U.S. lettuce production (Vegetables, 1988 Summary, Agricultural Statistics Board, NASS, USDA June 1989, p. 12).

23. No data were submitted on spinach in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on spinach harvested following soil and foliar applications with representative D, WP/D, WP, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. The current instruction limiting lindane application to spinach in the seedling stage is too vague. A more definite pre-harvest interval (PHI), expressed in terms of days or the height of the seedling, must appear on all labels with the spinach use pattern. Revised labeling must be submitted

TABLE A. (Continued).

that specify the total number of applications permitted per growing season and the time period between these applications. The data must be developed from field trials in CA, TX or OK, NJ, MD or VA, and CO or AR.

24. No data were submitted on broccoli in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on broccoli harvested following seed treatment, soil and foliar applications with representative D, WP/D, WP, FLC, SLC, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. Revised labeling must be submitted showing a pre-harvest interval (PHI), in terms of days, associated with the use of lindane applied to the soil around the base of the plant. Also, revised labeling must be submitted that specifies the total number of applications permitted per growing season for either the foliar or the soil (plant base) application method and the time period between these applications. The data must be developed from field trials in CA, TX or AZ, and OR.

25. No data were submitted on Brussels sprouts in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on Brussels sprouts harvested following seed treatment, soil, and foliar applications with representative D, WP/D, WP, FLC, SLC, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. Revised labeling must be submitted showing a pre-harvest interval (PHI), in terms of days, associated with the use of lindane applied to the soil around the base of the plant, and specifying the total number of applications permitted per growing season for either the foliar or the soil (plant base) application method and interval between these applications. The data must be developed from field trials in CA, NY, and OR.

26. Data on lindane residue in or on cabbage submitted in response to the Guidance Document do not satisfy requirements for this topic because insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on cabbage must submit the following additional data: Data depicting lindane residues of concern in or on cabbage harvested following seed treatment with a representative EC, FLC, or WP formulation, soil applications with a representative EC or WP formulation, and foliar application with a representative EC or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on cabbage 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 1982 U.S. cabbage acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 338).

TABLE A. (Continued).

27. No data were submitted on cauliflower in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on cauliflower harvested following seed treatment, soil, and foliar applications with representative D, WP/D, WP, FLC, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. Revised labeling must be submitted showing a pre-harvest interval (PHI), in terms of days, associated with the use of lindane applied to the soil around the base of the plant, and specifying the total number of applications permitted per growing season for either the foliar or the soil (plant base) application method and interval between these applications. The data must be developed from field trials in WA or OR, CA, FL, TX or AZ, NY, and MI.
28. No data were submitted on collards in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on collards harvested following soil and foliar applications with representative WP/D, WP, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. Revised labeling must be submitted showing a more definite pre-harvest interval (PHI), rather than the current restriction against applying lindane after the edible parts of the plant have appeared (since the edible part of the plant is the leaf, which appears as soon as the plant sprouts). In addition, revised labeling must specify the number of applications permitted per growing season for the foliar application method and the interval between these applications. The data must be developed from field trials in FL or GA or SC, TX or AZ, and NJ.
29. No data on kale were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on kale following soil and foliar application with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Revised labeling must be submitted showing a more definite pre-harvest interval (PHI), rather than the current limitation against applying lindane after the edible parts of the plant have appeared (since the edible part of the plant is the leaf, which appears as soon as the plant sprouts). In addition, revised labeling must specify the number of applications permitted per growing season for the foliar application method and the interval between these applications. Tests must be conducted in GA, CA, TX, and VA.
30. No data on beans (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane

TABLE A. (Continued).

residues of concern in or on beans (succulent and dried), bean vines and bean hay following seed treatment using a representative D, EC, WP, WP/D, or FLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in WI(32%), OR(22%), and MI(7%) or IL(6%) since these states accounted for ca. 70% of the 1988 snap bean production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on soybeans will be translated to data required for dried beans.

31. No data on peas (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on peas (succulent and dried), pea vines and pea hay following seed treatment using a representative D, EC, WP, WP/D, or FLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in WA(29%) or OR(12%), WI(17%) or MN (17%) and NY(4%) since these states collectively accounted for ca. 80% of the 1988 garden pea production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on soybeans will be translated to dried peas.

32. No data on soybeans (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on soybean grain, forage, and hay grown from seed treated using a representative D, EC, WP, WP/D, or FLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The tests must be conducted in IA(16%), IL(15%), LA(3%) or MS(3%) or AR(5%), NC(2%), and OH(6%), since these states and their bordering states accounted for >85% of the 1988 soybean production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989). Data on soybeans will be translated to data required for dried beans and dried peas.

33. No data on the processed products of soybeans were submitted in response to the Guidance Document. The following data remain outstanding: A processing study depicting the potential for concentration of lindane residues of concern in meal, hulls, soapstock, crude oil, refined oil, and grain dust processed from soybeans bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on soybeans.

34. No data on eggplants were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residue of concern in or on eggplants following

98

TABLE A. (Continued).

foliar application with a representative SLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA, FL, TX, and NJ.

35. No data on peppers were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residue of concern in or on peppers following soil and foliar application with a representative EC, WP, or WP/D formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA, FL, TX, NC, and NJ.

36. No data on tomatoes were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residue of concern in or on tomatoes following seed treatment, soil, and foliar application with a representative EC, WP, WP/D, D, or SLC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA, FL, OH or PA, NJ, IN, MI and SC or TN.

37. No tomato processing data were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in tomato juice, puree or catsup, and pomace (wet and dry) processed from tomatoes bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on tomatoes.

38. Data on lindane residue in or on cucumbers submitted in response to the Guidance Document do not satisfy requirements for this topic because insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on cucumbers must submit the following additional data: Data depicting lindane residues of concern in or on cucumbers harvested following seed treatment with a representative EC, FLC, WP/D, or WP formulation, soil applications with a representative EC, WP/D, or WP formulation, and foliar application with a representative D, SLC, EC, WP/D, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on cucumbers must be conducted in CA(11%), FL(6%), MI(19%), NJ(1%), NC(15%), TX(8%), and WI(7%) since these states accounted for ca. 67% of the 1988 U.S. cucumber production (Vegetables, 1988 Summary, Ag. Statistics Board, NASS, USDA June 1989, p. 40).

TABLE A. (Continued).

39. No data were submitted on melons in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on cantaloupes and watermelons harvested following soil and foliar applications with representative D, WP/D, WP, FLC, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Data on cantaloupes must be developed from field trials in CA, TX or AZ, IN, MI, and GA or SC. Data on watermelons must be developed from field trials in FL or GA, TX, and CA.

40. No data were submitted on pumpkins in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on pumpkins harvested following soil and foliar applications with representative D, WP/D, WP, FLC, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Current labels stipulate a pre-harvest interval (PHI) of 1 day, but also include a limitation against use after blossoms open. A pre-harvest interval, supported by residue data, must be established to eliminate this disparity. Data must be developed from field trials in CA, TX, IL, NJ, and OR.

41. No data were submitted on squash in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on squash harvested following soil and foliar applications with representative D, WP/D, WP, FLC, SLIC or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Current labels indicate a 1-day PHI, but they also include a note that late foliar application may result in reduction of quality at harvest. A revised PHI, supported by adequate residue data, should be proposed that would eliminate the quality loss problem. Data on summer squash must be developed from field trials in CA, FL, MI, TX, OR, NY or NJ or MA, and GA or SC. Data on at least two different kinds of winter squash are required. The data on winter squash should be generated from areas where these squash are grown commercially. Alternatively, revised labeling can be submitted in which the types of squash to be treated with lindane are limited to those for which adequate residue data have been generated.

TABLE A. (Continued).

42. Data on lindane residue in or on apples submitted in response to the Guidance Document do not satisfy requirements for this topic because insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on apples must submit the following additional data: Data depicting lindane residues of concern in or on apples harvested following bark application with a representative EC or WP formulation and foliar application with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on apples must be conducted in CA(7%), MI(9%), NY(10%), NC(4%), and WA(43%) since these states accounted for ca. 73% of the 1988 U.S. apple production (Agricultural Statistics Board, NASS, USDA, Aug 1989).

43. A processing study depicting the potential for concentration of lindane residues of concern in wet and dry pomace, and apple juice from the processing of apples bearing measurable, weathered residues following foliar application. If residues concentrate in any processed product appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on apples.

44. No data were submitted on pears in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on pears harvested following bark and foliar applications with representative RTU, PrL, FLC, or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. The dosage rate for foliar application should be expressed in terms of pounds per 100 gallons (lb/100 gal) and as a range in pounds per acre (lb/A). The dosage in terms of lb/A is based on the number of gallons of dilute spray needed to spray one acre of trees to the point of runoff or the equivalent amount of product per acre in concentrate sprays. A prohibition against grazing livestock on cover crops beneath treated trees must be added to all lindane end-use products with directions for use on pears. Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications for both the foliar treatment and the bark treatment methods of application. Data on pears must be developed from field trials in CA, MI, NY, and WA.

45. No data were submitted on apricots in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on apricots harvested following bark applications with representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The dosage rate for bark

TABLE A. (Continued).

application should be expressed in terms of pounds per 100 gallons (lb/100 gal) and as a range in pounds per acre (lb/A). The dosage in terms of lb/A is based on the number of gallons of dilute spray needed to spray one acre of trees to the point of runoff. A prohibition against grazing livestock on cover crops beneath treated trees must be added to lindane end-use products with directions for use on apricots. Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications for both the bark treatment method of application. Data on apricots must be developed from field trials in CA, MI, CO, AZ, WA or OR or ID.

46. No data were submitted on cherries in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on cherries harvested following bark, soil, and foliar applications with representative FLC or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels. The dosage rate for both foliar and bark applications should be expressed in terms of pounds per 100 gallons (lb/100 gal) and as a range in pounds per acre (lb/A). The dosage in terms of lb/A is based on the number of gallons of dilute spray needed to spray one acre of trees to the point of runoff (for foliar and bark treatment) or the equivalent amount of product per acre in concentrate sprays (for foliar application only). A prohibition against grazing livestock on cover crops beneath treated trees must be added to lindane end-use products with directions for use on cherries. Revised labeling must be submitted that specifies the total number of foliar applications permitted per season and the interval between these applications. Data on cherries must be developed from field trials in CA, MI, NY or PA, UT or MT or ID, and WA or OR.

47. Data on lindane residue in peaches submitted in response to the Guidance Document do not satisfy requirements for this topic because no data reflected foliar applications and insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on peaches must submit the following additional data: Data depicting lindane residues of concern in or on peaches harvested following bark applications with a representative EC or WP formulation and foliar application with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on peaches must be conducted in CA(59%), MI(2%), PA(3%) or NJ(3%), SC(13%) or GA(5%), and WA(2%) since these states accounted for ca. 70-80% of the 1988 U.S. peach production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).

48. No data were submitted on plums (fresh prunes) in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on plums (fresh prunes) harvested following foliar applications with representative FLC or EC formulations. Residue data must reflect use directions and maximum registered application rates specified on current product labels.

TABLE A. (Continued).

Residue data must include results from treatment with EC formulations, since residues would be expected to be higher from that type of formulation. The dosage rate for foliar applications should be expressed in terms of pounds per 100 gallons (lb/100 gal) and as a range in pounds per acre (lb/A). The dosage in terms of lb/A is based on the number of gallons of dilute spray needed to spray one acre of trees to the point of runoff (for foliar treatment) or the equivalent amount of product per acre in concentrate sprays. A prohibition against grazing livestock on cover crops beneath treated trees must be added to lindane end-use products with directions for use on plums (fresh prunes). Revised labeling must be submitted that specifies the total number of foliar applications permitted per season and the interval between these applications. Data on plums (fresh prunes) must be developed from field trials in CA, ID, MI, and WA or OR.

49. No processing data for dried prunes were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in dried prunes processed from fresh prunes bearing measurable, weathered residues. If residues concentrate in this product, an appropriate food additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on plums (fresh prunes).

50. Data on lindane residues in or on grapes submitted in response to the Guidance Document do not satisfy requirements for this topic because insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on grapes must submit the following additional data: Data depicting lindane residues of concern in or on grapes harvested following foliar applications with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on grapes must be conducted in CA(92%), NY(3%), and WA(3%) since these states accounted for ca. 98% of the 1988 U.S. grape production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).

51. Data from the processing study submitted in response to the Guidance Document do not satisfy the requirements for the topic because samples of grapes bearing nondetectable residues were used in the study. The following additional data are required: A processing study depicting the potential for concentration of lindane residues of concern in wet and dry pomace, raisins, raisin waste, and grape juice from the processing of grapes bearing measurable, weathered residues. If residues concentrate in any processed product appropriate food/feed additive tolerances must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on grapes.

TABLE A. (Continued).

52. No data on strawberries were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on strawberries following foliar application with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Revised labeling that specifies the total number of foliar applications permitted per season and the interval between these applications must be submitted. Tests must be conducted in CA, FL, NY or OH, and OR or WA.

53. Data on lindane residues in or on pecans submitted in response to the Guidance Document do not satisfy requirements for this topic because they do not reflect delayed dormant uses and are not representative of the major pecan growing regions. Also, insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on pecans must submit the following additional data: Data depicting lindane residues of concern in or on pecans harvested following foliar and delayed dormant applications with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Samples should be ground in an Ultra Centrifugal Mill prior to extraction with a Polytron or Omni-Mixer. Tests on pecans must be conducted in GA(38%), IA(10%), OK(16%), and TX(12%) since these states accounted for ca. 76% of the 1988 U.S. pecan production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).

54. No data concerning residues in or on barley grain, barley forage, and barley straw (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit appropriate supporting residue data depicting lindane residues of concern in or on barley grain, barley forage, and barley straw following seed treatment. Residue data requested for wheat grain, wheat forage, and wheat straw will be translated to satisfy the requirements for barley grain, barley forage, and barley straw.

55. No processing data on barley grain were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data from the wheat processing study will be translated to satisfy the requirements for a barley processing study.

56. No data concerning field corn, sweet corn or popcorn (seed treatment) were submitted in response to the Guidance Document. The following data requirements remain outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on field corn, sweet corn, and popcorn, corn forage, and corn fodder grown from seed treated using a representative D, WP/D, FLC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in IA(18%), IL(14%), NE(17%), OH(5%), and TX(3%) since

TABLE A. (Continued).

theses states and their bordering states accounted for >80% of the 1988 corn production (Ag. Statistics Board, NASS, USDA Crop Database. Aug. 1989).

57. No corn processing data were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in wet milled products (starch, crude oil, and refined oil) and in dry milled products (grits, meal, flour, and crude and refined oils) and grain dust processed from corn bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on corn grain.
58. No data concerning residues in or on oat grain, oat forage, and oat straw (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit appropriate supporting residue data depicting lindane residues of concern in or on oat grain, oat forage, and oat straw following seed treatment. Residue data requested for wheat grain, wheat forage, and wheat straw will be translated to satisfy the requirements for oat grain, oat forage, and oat straw.
59. No processing data on oat grain were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data from the wheat processing study will be translated to satisfy the requirements for an oat grain processing study.
60. No data concerning residues in or on rye grain, rye forage, and rye straw (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit appropriate supporting residue data depicting lindane residues of concern in or on rye grain, rye forage, and rye straw following seed treatment. Residue data requested for wheat grain, wheat forage, and wheat straw will be translated to satisfy the requirements for rye grain, rye forage, and rye straw.
61. No processing data on rye grain were submitted in response to the Guidance Document. Data from the wheat processing study will be translated to satisfy the requirements for a rye grain processing study.

TABLE A. (Continued).

62. No data on sorghum grain, sorghum forage, and sorghum fodder (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on sorghum grain, sorghum forage, and sorghum fodder reflecting seed treatment. Data required for corn grain, corn forage, and corn fodder will be translated to satisfy requirements for sorghum grain, sorghum forage, and sorghum fodder.

63. No sorghum processing data were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in milled products (flour and starch) and grain dust processed from sorghum bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on sorghum grain.

64. No data on wheat grain, wheat forage, and wheat straw (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on wheat grain, forage, hay and straw grown from seed treated using a representative D, EC, WP/D, FLC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in KS(18%), ND(6%), OK(10%), OH(3%), GA(1%) or NC(1%) or SC(1%), and WA(7%) since these states and their bordering states accounted for ca. 80% of the 1988 wheat production (Ag. Statistics Board, NASS, USDA Crop Database. Aug. 1989). Data on wheat will be translated to data required for barley, oats, and rye.

65. No wheat processing data were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in milled products (bran, flour, middlings, and shorts) and grain dust processed from wheat bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on wheat grain. Data on wheat will be translated to data required for barley, oats, and rye.

66. No data on sudangrass (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on sudangrass grown from seed treated using a representative D, EC, WP/D,

TABLE A. (Continued).

FLC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA and TX.

67. No data on alfalfa forage and hay (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on alfalfa forage and hay grown from seed treated using a representative D, EC, WP/D, FLC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA(10%), CO(4%), IA(8%), ID(5%), and PA(4%) since these states and their bordering states accounted for ca. 70% of the 1988 alfalfa production (Ag. Statistics Board, NASS, USDA, Crop Database, Aug. 1989). Data for alfalfa will be translated to data required for clover.

68. No data on clover forage and hay (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on clover forage and hay. Data required for alfalfa forage and hay will be translated to satisfy requirements for clover forage and hay.

69. No data on cottonseed (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on cottonseed grown from seed treated using a representative D, WP/D, FLC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in AR(7%), CA(18%), MS(12%), and TX(34%) since these states accounted for ca. 70% of the 1988 cotton production (Ag. Statistics Board, NASS, USDA Crop Database, Jan. 1989).

70. No processing data on cottonseed were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in meal, hulls, soapstock, crude oil, and refined oil processed from cottonseed bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on cottonseed.

71. No data on flax seed (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for

TABLE A. (Continued).

lindane residues of concern in or on flax seed grown from seed treated using a representative D, FLC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in ND(80%) and SD(13%), since these states accounted for ca. 93% of the 1988 flax production (Ag. Statistics Board, NASS, USDA Crop Database, Jan. 1989).

72. No processing data on flax seed were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in meal (linseed) processed from flax seed bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on flax seed.

73. No data on okra were submitted in response to the Guidance Document. The following data requirement remains outstanding: Data depicting lindane residues of concern in or on okra following seed treatment and soil applications with a representative D, WP/D, FLC, WP, or EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests on okra must be conducted in TX, FL or GA or AL.

74. No data on safflower seed (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on safflower seed grown from seed treated using a representative D, WP/D, FLC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in CA(76%) and MT(17%) since these states accounted for ca. 93% of the 1982 safflower production (1982 Census of Agriculture, Vol. 1, Part 51, p. 317).

75. No processing data on safflower seed were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in meal, crude oil, and refined oil processed from safflower seeds bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on safflower seeds.

TABLE A. (Continued).

76. No data on sunflower seed (seed treatment) were submitted in response to the Guidance Document. The following data requirement remains outstanding: The registrant must propose tolerances and submit data for lindane residues of concern in or on sunflower seed grown from seed treated using a representative D, WP/D, FLC, EC, or WP formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. Tests must be conducted in ND(82%) and TX(2%) since these states accounted for ca. 85% of the 1988 sunflower production (Ag. Statistics Board, NASS, USDA Crop Database, Aug. 1989).

77. No processing data on sunflower seed were submitted in response to the Guidance Document. The following data requirement remains outstanding: A processing study depicting the potential for concentration of lindane residues of concern in meal, hulls, crude oil, and refined oil processed from sunflower seeds bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed. The need for a processing study may be waived if field residue tests using rates exaggerated by the highest theoretical concentration factor for the processed products indicate that no detectable residues of concern occur in or on sunflower seeds.

78. Data on tobacco submitted in response to the Guidance Document do not satisfy requirements for the topic because insufficient data are available to assess the adequacy of current label directions. Parties interested in retaining registered uses on tobacco must submit the following additional data: Data depicting lindane residues of concern in or on tobacco harvested following soil applications (applied to tobacco transplant beds in transplanting water) with a representative EC formulation. Residue data must reflect use directions and maximum registered application rates specified on current product labels. If residues of ≥ 0.1 ppm are found in or on green, freshly harvested tobacco, then pyrolysis products derived from the active ingredient must be characterized. Tests on tobacco must be conducted in NC(40%) and KY(26%), since these states and their neighboring states accounted for >70% of the 1988 U.S. tobacco production (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989).

79. The nature of the residue in animals is not understood. On receipt of the requested ruminant and poultry metabolism data: (i) the adequacy of the existing tolerances for residues in animal products will be determined, with consideration of any newly found metabolite of toxicological concern; (ii) the expected dietary intake for poultry, beef cattle, dairy cattle, and swine will be calculated; and (iii) the need for additional feeding and dermal treatment studies (ruminants) will be reevaluated.