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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 8 1990

MEMORANDUM

SUBJECT: Naled Product Chemistry and Residue Chemistry Registration Standard Updates.

FROM: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch (DEB)
Health Effects Division (H7509C)

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 updates to the Product and Residue Chemistry Chapters of the Naled Registration Standard prepared by Dynamac Corporation under supervision of the Dietary Exposure Branch, HED. They have undergone secondary review in the Dietary Exposure Branch and have been revised to reflect Agency policies.

These documents provide an in-depth analysis of the status of the Naled Product and Residue Chemistry data bases as of 03/05/90. Revised data requirement tables are included.

Please note that Confidential Business Information accompanies the Product Chemistry Update as Appendices A, B, C, D and E.

If you need additional input please advise.

Attachment 1: Naled Product Chemistry Registration Standard Update

Attachment 2: Confidential Appendices A, B, C, D and E.

Attachment 3: Naled Residue Chemistry Registration Standard Update

cc (with attachments 1, 2 & 3): W. Smith, Naled Registration Standard file, Naled Subject File, C. Furlow (PIB/FOD), J. Burrell (FOD), Dynamac.

cc (without attachments): RF, Circ.(8)

DYNAMAC
CORPORATION

Final Report

NALED
Task 4: Product Chemistry Registration Standard Update

Contract No. 68-D8-0080

MAY 7, 1990

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
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NALED

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

INTRODUCTION

A Product Search Listing (PRD1) conducted 1/30/90 identifies four registered manufacturing-use products (MPs) of naled, all of which are 90% technical products (Ts). EPA registration numbers have changed; registration numbers from the Index to Pesticide Chemicals dated 5/2/89 and current registration numbers from the Product Search Listing dated 1/30/90 are presented in Table 1.

Table 1. Naled manufacturing-use products.

Product	EPA Reg. No. Transferred from	Current	Registrant
90% T	N/A	5481-198	AMVAC Chemical Corp.
90% T	N/A	59639-43	Valent U.S.A. Corp.
Dibrom® 90% T	239-2297	62499-14	Chevron Chemical Co.
Naled® 90% T	239-1633	62499-38	Chevron Chemical Co.

The Chevron Ortho Dibrom® 90% T is labeled for export only. The two Chevron products will be identified in this document by their current EPA Reg. Nos., 62499-14 and 62499-38.

The Naled Guidance Document dated 6/83 identifies outstanding data requirements for several product chemistry topics concerning the two Chevron products. In response to these requirements, Chevron Chemical Company submitted data (1984; MRIDs 00138602, 00138846, and 00144887) for the 90% T (EPA Reg. No. 62499-38). Chevron has submitted Confidential Statements of Formula (CSF) dated 12/23/83 for both 90% Ts (EPA Reg. Nos. 62499-14 and 62499-38). These data are reviewed below for their adequacy in fulfilling the outstanding data requirements.

AMVAC Chemical Corp., in 1985, applied for a separate registration for the TGAI it produces for Chevron. J. Garbus (DEB No. 1197, 10/16/85) determined that the data submitted by AMVAC were the same data submitted in 1984 by Chevron for its 90% T, and that the data could be used to support registration of the AMVAC technical. Therefore, for purposes of this Update, the data in MRIDs 00138602 and 00138846 are applied to requirements for the AMVAC 90% T (EPA Reg No. 5481-198) as well as the Chevron 90% T.

No data have been submitted for the Valent 90% T (EPA Reg. No. 5481-198).

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 D, "Product Chemistry Data Requirements". These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of naled.

	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 Naled Product Chemistry data are required:

- For the Chevron 90% T (EPA Reg. No. 62499-38) and the AMVAC 90% T (EPA Reg. No. 5481-198), data must be submitted pertaining to discussion of the formation of impurities, preliminary analysis, certified limits, and two physical and chemical characteristics: the dissociation constant and flammability.

- For the other Chevron 90% T (EPA Reg. No. 62499-14), data must be submitted pertaining to all product chemistry topics with the exception of enforcement analytical methods. Alternatively, if Chevron's two 90% Ts are the same TGAI, the registrant must document this.

- For the Valent 90% T (EPA Reg. No. 59639-43), data must be submitted pertaining to all product chemistry topics.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Composition

The Naled Guidance Document dated 6/83 requires no additional generic or product-specific data concerning this topic for Chevron's 90% T products. Chevron submitted CSFs for the two products dated 12/23/83; these data are presented in Confidential Appendix A. We note that these two CSFs are identical. In addition, the CSFs designate these as alternate formulations and do not reflect the current EPA Reg. Nos.; therefore, updated CSFs

are required for these formulations and the basic formulation. DEB has determined that adequate data are available for the AMVAC 90% T (J. Garbus, DEB No. 1197, 10/16/85).

No data pertaining to product composition have been submitted for the Valent 90% T (EPA Reg. Nos. 5481-198); all data requirements concerning this topic are still outstanding for this product.

61-2. Beginning Materials and Manufacturing Process

Although the Naled Guidance Document dated 6/83 indicates that data are adequate for Chevron products, the registrant has submitted additional data (1984; MRIDs 00138602 and 00138846) pertaining to the beginning materials and manufacturing process for its 90% T (EPA Reg. No. 62499-38); the data apply to the AMVAC 90% T, also. Details are presented in Confidential Appendix B. These data meet the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding beginning materials and the production process for the Chevron 90% T (EPA Reg. No. 62499-38) and the AMVAC 90% T.

No data pertaining to the beginning materials and the manufacturing process have been submitted for the Chevron 90% T (EPA Reg. No. 62499-14) or the Valent 90% T (EPA Reg. No. 5481-198); data requirements for this topic are still outstanding for this product.

61-3. Discussion of the Formation of Impurities

The Naled Guidance Document dated 6/83 specifies additional generic and product-specific data requirements for naled regarding discussion of formation of impurities. In response, Chevron Chemical Company (1984; MRID 00138846) submitted a discussion of the formation of impurities for its 90% T (EPA Reg. No. 62499-38); the data apply to the AMVAC 90% T, also. These data are discussed in Confidential Appendix C. These data do not satisfy the requirements of 40 CFR §158.167 (Guidelines Reference No. 61-3) regarding the formation of impurities in the Chevron 90% T (EPA Reg. No. 62499-38) or the AMVAC 90% T because information was not provided concerning the possible degradation of ingredients in the product after production; post-production reactions between the ingredients in the product; possible contamination from packaging materials or production equipment; and process control, purification and quality control measures. Additional data are required.

No information pertaining to discussion of the formation of impurities has been submitted for the Chevron 90% T (EPA Reg. No. 62499-14) or the Valent 90% T (EPA Reg. No. 59639-43); data

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requirements concerning this topic are still outstanding for these products.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Naled Guidance Document dated 6/83 specifies generic and product-specific data requirements for naled regarding preliminary analysis. In response, Chevron Chemical Company (1984; MRID 00138846) submitted data pertaining to its 90% T (EPA Reg. No. 62499-38); the data also pertain to the AMVAC 90% T. These data are presented in Confidential Appendix D. These data do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the Chevron 90% T (EPA Reg. No. 62499-38) because analyses were reported for only four batches of the product as produced by the source listed on the CSF, and because the analytical methods used and related validation data were not presented. The registrant must provide preliminary analyses of the active ingredient and all impurities present at 0.1% or greater in at least five separate batches. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. In addition, the registrant should explain the reason for including the results of the analysis of a single batch of technical naled manufactured by a source not listed on the CSF; if the 90% T is also produced by another source in addition to that listed on the CSF, additional preliminary analysis data will be required for the naled TGAI produced by that source. Additional data are required.

No preliminary analysis data have been submitted for the other Chevron 90% T (EPA Reg. No. 62499-14) or for the Valent 90% T (EPA Reg. No. 59639-43); all data requirements concerning this topic are still outstanding for this product.

62-2. Certified Limits

The Naled Guidance Document dated 6/83 specifies additional generic and product-specific data requirements for naled regarding certification of ingredient limits. In response, Chevron Chemical Company submitted CSFs for its 90% Ts (EPA Reg. Nos. 62499-38 and 62499-14). These data are reviewed in Confidential Appendix A. The certified limits data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) for either product because the registrant has not provided nominal concentrations limits for two impurities which are themselves active ingredients, and a nominal concentration was not provided for the active ingredient, naled. Additional

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data are required. New information should be submitted on EPA Form 8570-4 (Rev. 2/85).

In addition, the CSFs for the Chevron 90% Ts identify the formulations as alternate; if these represent an alternate formulation, the registrant should identify the basic formulation and submit pertinent product chemistry data.

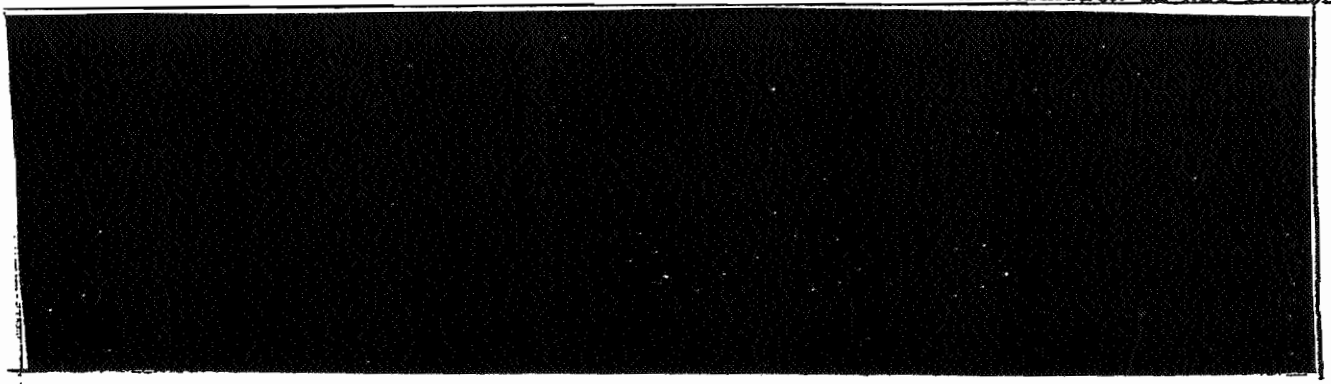
DEB has determined that data are available to satisfy this requirement for the AMVAC 90% T (J. Garbus, DEB No. 1197, 10/16/85).

No certified limits data have been submitted for the Valent 90% T (EPA Reg. No. 59639-43); all data requirements for this topic are still outstanding for this product.

62-3. Enforcement Analytical Methods

The Naled Guidance Document dated 6/83 specifies generic and product-specific data requirements for naled regarding analytical methods to verify certified limits. In response, Chevron Chemical Company (1984; MRIDs 00138602 and 00138846) submitted data pertaining to its 90% T (EPA Reg. No. 62499-38); these data apply to the AMVAC 90% T, also. The method for determination of the active ingredient is discussed below, while the methods for determination of the impurities are discussed in Confidential Appendix E.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED



The analytical methods Chevron Chemical Company has submitted regarding enforcement for the 90% T (EPA Reg. No. 62499-38) satisfy the requirements of 40 CFR 158.180 (Guideline Reference No 62-3). These methods also satisfy the requirements of 40 CFR 158.180 (Guideline Reference No 62-3) for the other 90% T (EPA Reg. No. 62499-14), based on the CSF dated 12/12/83, and for the AMVAC 90% T (EPA Reg. No. 5481-198). No additional data are required.

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No analytical methods have been submitted for the Valent 90% T (EPA Reg. No. 59639-43); all data requirements for this topic are still outstanding for this product.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Naled Guidance Document dated 6/83 requires additional data pertaining to specific gravity, dissociation constant, octanol/water partition coefficient, pH, and flammability for the 90% T products. In response, Chevron Chemical Company (1984; MRID 00138602) has submitted data for the 90% T (EPA Reg. No. 62499-38); these data apply to the AMVAC 90% T, also.

Specific gravity for the technical grade of the active ingredient (TGAI) was determined to be 1.9711 at 20 C using CIPAC method MT 3.2.1. Using a ^{14}C radiolabel, the octanol/water coefficient (K_{ow}) of the purified active ingredient (PAI) was determined to be 150 (log K_{ow} = 2.18) for 500 ppm initial concentration in octanol and 92 (log K_{ow} = 1.96) for 100 ppm initial concentration in octanol. Although the product has very low solubility in water, the pH, measured in accordance with ASTM Method E-70, was 1.9-1.8 for a 10% v/v solution of the TGAI in water and 3.0-2.6 for a 5% v/v solution of the PAI in water. These data satisfy the requirements of 40 CFR 158.190 (Guideline Reference Nos. 63-7, 11, and 12) regarding specific gravity, octanol/water partition coefficient, and pH for the Chevron 90% T (EPA Reg. No. 62499-38) and the AMVAC 90% T (EPA Reg. No. 5481-198). Additional data were submitted regarding corrosion characteristics; aluminum exhibited "good" resistance to naled with a corrosion rate of 2 mils per year (MRID 00144887). No data were submitted concerning dissociation constant and flammability. Additional data are required.

Chevron Chemical Company has not submitted data for the other 90% T (EPA Reg. No. 62499-14) concerning the five physicochemical properties required by the Guidance Document. These data requirements remain outstanding for the product. If Chevron provides documentation that their two 90% Ts are the same TGAI, additional data for EPA Reg. No. 62499-14 may not be required.

No data pertaining to physical and chemical characteristics have been submitted for Valent 90% T (EPA Reg. No. 59639-43); all data requirements for this topic are still outstanding for this product.

Product Chemistry Citations (used):

00138602 Chevron Chemical Co. (1984) Chevron Naled Technical. (Compilation; unpublished study received Jan 18, 1984 under 239-1633; CDL:252279-A)

00138846 Chevron Chemical Co. (1984) Chevron Naled Technical: Product Chemistry. (Compilation; unpublished study received Jan 18, 1984 under 239-1633; CDL:252280-A)

00144887 Chevron Chemical Co. (1984) [Naled Technical Product Chemistry Data]. Unpublished study. 4 p.

Product Chemistry Citations (not used):

The following references were not used because they contain information that is duplicated in the above-cited documents or that is not required by the Guidance Document.

00155114 Flay, R. (1985) Vapor Pressure and Boiling Range of Technical Naled: File No. 760.15. Unpublished study prepared by Chevron Chemical Co. 3 p.

41376901 Jackson, R. E. (1989) Storage Stability Study of Dibrom 14 (PN-03290). Unpublished study prepared by Chevron Chemical Company 7 p.

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

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Partially	00138602 00138846	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	00138846	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	TGAI	Partially	00138846	Yes[6]
Physical and Chemical Characteristics[7]				
63-2. Color	TGAI	Partially	N/A	Yes[8]
63-3. Physical State	TGAI	Partially	N/A	Yes[11]
63-4. Odor	TGAI	Partially	N/A	Yes[8]
63-5. Melting Point	TGAI	N/A	N/A	No[9]
63-6. Boiling Point	TGAI	Partially	N/A	Yes[8]
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Partially	00138602	Yes[10]
63-8. Solubility	TGAI or PAI	Partially	N/A	Yes[8]
63-9. Vapor Pressure	TGAI or PAI	Partially	N/A	Yes[8]
63-10. Dissociation Constant	TGAI or PAI	No	N/A	Yes[11]
63-11. Octanol/Water Partitioning Coefficient	PAI	Partially	00138602	Yes[10]
63-12. pH	TGAI	Partially	00138602	Yes[10]
63-13. Stability	TGAI	Partially	N/A	Yes[8]
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

1. The following requirements pertain to the Chevron Chemical Company 90% Ts (EPA Reg. No. 62499-14 and 62499-38), AMVAC chemical Corporation 90% T (EPA Reg. No. 5481-198), and Valent U.S.A. Corporation 90% T

TABLE A. (Continued).

(EPA Reg No. 59639-43). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Naled Manufacturing-Use Products", for registered technical 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. Valent has not responded to data requirements pertaining to their 90% T listed in Footnote 1; Chevron has not responded with data for their 90% T (EPA Reg. No. 62499-14). The following information is required for these products: (i) the name and address of the producer of the technical grade of the active ingredient; (ii) the brand name, trade name or other commercial designation, the name and address of the producer, and information concerning the composition of each starting material; (iii) a general characterization of the process (e.g., batch or continuous); (iv) a flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, and the duration of each step of the process and of the entire process; (v) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (vi) a description of the equipment used; (vii) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; (viii) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced); and (ix) a description of the procedures used to assure consistent composition of the substance produced (quality control methods). Alternative to submitting data for this topic, Chevron may document that their two 90% Ts are the same TGAI. Additional data submitted by Chevron pertaining to the 90% T (EPA Reg. No. 62499-38) and the AMVAC 90% T are acceptable. However, data submitted by Chevron on preliminary analysis and certified limits suggest that this product is manufactured by more than one supplier. (The CSFs for the Chevron 90% Ts list only one supplier.) If either product is manufactured by another supplier, all data requirements pertaining to beginning materials and manufacturing process are required for that supplier, as stated above.

5. No data have been submitted on this topic by Valent for their products listed in Footnote 1, or by Chevron for the 90% T (EPA Reg. No. 62499-14). For these products, a discussion must be submitted regarding the origin of the following potential impurities: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may

TABLE A. (Continued).

occur during production, the possible degradation of ingredients after production, post-production reactions between ingredients, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. Alternateive to submitting a full set of data for this topic, Chevron may document that their two 90% Ts are the same TGAI. Chevron has responded to the Guidance Document for the 90% T (EPA Reg No. 62499-38); the data also apply to the AMVAC 90% T (EPA Reg. No. 5481-198). However the submitted discussion is not adequate. The registrant must submit additional information regarding the possible degradation of ingredients after production, post-production reactions between ingredients, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures.

6. No data have been submitted on this topic by Valent for their products listed in Footnote 1, or by Chevron for the 90% T (EPA Reg. No. 62499-14). For these products, five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. If the product is produced by a batch process, five separate batches should be represented in preliminary analyses. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If Chevron provides documentation that their two 90% Ts are the same TGAI, the data required for Chevron 90% T (EPA Reg. No. 62499-38 may apply to their other 90% T (EPA Reg. No. 62499-14). Chevron has responded to the Guidance Document pertaining to its 90% T (EPA Reg. No. 62499-38); these data also apply to the AMVAC 90% T (EPA Reg. No. 5481-198). Chevron has submitted preliminary analysis data of batches manufactured by two different suppliers. The registrant must submit preliminary analysis data based on five or more representative samples from a single supplier. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. If an additional supplier is producing this product, then all data requirements for this topic are required for that supplier, as stated above.

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.

TABLE A. (Continued).

8. As per the Guidance Document, adequate data have been submitted for the Chevron products; DEB has determined that these data apply to the AMVAC 90% T (EPA Reg. No. 5481-198) as well (J. Garbus, DEB No. 1197, 10/16/85). Valent has not submitted data pertaining to their products listed in Footnote 1 and must address this data requirement.

9. Data on melting point are not required since the technical product is a liquid at room temperature.

10. No data have been submitted for this topic for the Valent 90% T or the Chevron 90% T (EPA Reg. No. 62499-14; this data requirement must be fulfilled for these products. Chevron has responded to the Guidance Document for the 90% T (EPA Reg. No. 62499-38); the data submitted are adequate for this topic and apply also to the AMVAC 90% T (EPA Reg No. 5481-198).

11. No data have been submitted on this topic by AMVAC, Valent, or Chevron for their products listed in Footnote 1. Data for this topic are required for these products.

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

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Composition	MP	Partially	N/A	Yes[4]
61-2. Beginning Materials & Production/Formulation Process	MP	Partially	00138602 00138846	Yes[5]
61-3. Formation of Impurities	MP	Partially	00138846	Yes[6]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	MP	Partially	00138846	Yes[7]
62-2. Certified Limits	MP	Partially	00138846	Yes[8]
62-3. Enforcement Analytical Methods	MP	Partially	00138602 00138846	Yes[9]
Physical and Chemical Characteristics[10]				
63-2. Color	MP	Partially	N/A	Yes[11]
63-3. Physical State	MP	Partially	N/A	Yes[11]
63-4. Odor	MP	Partially	N/A	Yes[11]
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	00138602	Yes[12]
63-12. pH	MP	Partially	00138602	Yes[12]
62-14. Oxidizing or Reducing Action	MP	Partially	N/A	Yes[11]
62-15. Flammability	MP	No	N/A	Yes[13]
63-16. Explodability	MP	Partially	N/A	Yes[11,14]
63-17. Storage Stability	MP	Partially	N/A	Yes[11]
63-18. Viscosity	MP	Partially	N/A	Yes[11,15]
63-19. Miscibility	MP	Partially	N/A	Yes[11,16]
63-20. Corrosion Characteristics	MP	Partially	N/A	Yes[11]
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

TABLE B. (Continued).

1. The following requirements pertain to the Chevron Chemical Company 90% Ts (EPA Reg. No. 62499-14 and 62499-38), AMVAC chemical Corporation 90% T (EPA Reg. No. 5481-198), and Valent U.S.A. Corporation 90% T (EPA Reg No. 59639-43). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Naled Technical Grade of the Active Ingredient", for those manufacturing-use products which consist only of the TGAI.

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. The CSFs submitted for the Chevron 90% Ts (EPA Reg. Nos. 62499-38 and -14) designate these as alternate formulations and do not reflect the current EPA Reg. Nos.; therefore, updated CSFs are required for these formulations and the basic formulation. DEB has determined that adequate data are available for the AMVAC 90% T (J. Garbus, DEB No. 1197, 10/16/85). Valent has not submitted data pertaining to their product listed in Footnote 1. If these products consists of the technical grade of the active ingredient only or are produced by an integrated system, the following information must be provided: (i) the CA-approved chemical name, CAS Registry Number, any common names, the nominal concentration, upper and lower certified limits in accordance with 40 CFR §158.175, and the purpose of each active and inert ingredient in the product; (ii) the molecular, structural and empirical formulas, and the molecular weight or weight range of each active ingredient in the product; (iii) the chemical name and nominal concentration of each impurity of toxicological significance associated with the active ingredient or present in any sample at a level equal to or greater than 0.1% by weight of the TGAI; and (iv) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that are not characterized. Impurities must be identified as such. If these products are produced from an EPA-registered product, the following information must be provided: (i) the chemical and common name of each active ingredient as listed on the source product, its nominal concentration in the product based upon the nominal concentration in the source product, and upper and lower certified limits in accordance with 158.175; (ii) the CA-approved chemical name of each inert ingredient in the product, its CAS Registry Number, any common names, nominal concentration, purpose, and upper and lower certified limits in accordance with 40 CFR §158.175; and (iii) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that cannot be characterized.

5. Valent has not responded to data requirements pertaining to their 90% T listed in Footnote 1; Chevron has not responded with data for their 90% T (EPA Reg. No. 62499-14). The following information is required

TABLE B. (Continued).

for these products: (i) the name and address of the producer of the technical grade of the active ingredient; (ii) the brand name, trade name or other commercial designation, the name and address of the producer, and information concerning the composition of each starting material; (iii) a general characterization of the process (e.g., batch or continuous); (iv) a flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, and the duration of each step of the process and of the entire process; (v) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (vi) a description of the equipment used; (vii) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; (viii) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced); and (ix) a description of the procedures used to assure consistent composition of the substance produced (quality control methods). Alternative to submitting data for this topic, Chevron may document that their two 90% Ts are the same TGAI. Additional data submitted by Chevron pertaining to the 90% T (EPA Reg. No. 62499-38) and the AMVAC 90% T are acceptable. However, data submitted by Chevron on preliminary analysis and certified limits suggest that this product is manufactured by more than one supplier. (The CSFs for the Chevron 90% Ts list only one supplier.) If either product is manufactured by another supplier, all data requirements pertaining to beginning materials and manufacturing process are required for that supplier, as stated above.

6. No data have been submitted on this topic by Valent for their products listed in Footnote 1, or by Chevron for the 90% T (EPA Reg. No. 62499-14). For these products, a discussion must be submitted regarding the origin of the following potential impurities: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur during production, the possible degradation of ingredients after production, post-production reactions between ingredients, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. Alternateive to submitting a full set of data for this topic, Chevron may document that their two 90% Ts are the same TGAI. Chevron has responded to the Guidance Document for the 90% T (EPA Reg No. 62499-38); the data also apply to the AMVAC 90% T (EPA Reg. No. 5481-198). However the submitted discussion is not adequate. The registrant must submit additional information regarding the possible degradation of ingredients after production, post-production reactions between ingredients, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures.

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TABLE B. (Continued).

7. No data have been submitted on this topic by Valent for their products listed in Footnote 1, or by Chevron for the 90% T (EPA Reg. No. 62499-14). For these products, five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. If the product is produced by a batch process, five separate batches should be represented in preliminary analyses. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If Chevron provides documentation that their two 90% Ts are the same TGAI, the data required for Chevron 90% T (EPA Reg. No. 62499-38 may apply to their other 90% T (EPA Reg. No. 62499-14). Chevron has responded to the Guidance Document pertaining to its 90% T (EPA Reg. No. 62499-38); these data also apply to the AMVAC 90% T (EPA Reg. No. 5481-198). Chevron has submitted preliminary analysis data of batches manufactured by two different suppliers. The registrant must submit preliminary analysis data based on five or more representative samples from a single supplier. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. If an additional supplier is producing this product, then all data requirements for this topic are required for that supplier, as stated above.

8. No data have been submitted for the Valent product listed in Footnote 1. For these products, the registrant must propose upper and lower limits for each active and inert ingredient, if such limits would differ from the standard certified limits determined by the Agency according to 40 CFR §158.175(b)(2). Also, if the manufacturing use product contains the technical grade of the active ingredient only or is produced by an integrated system, upper limits must be proposed for each toxicologically significant impurity associated with the active ingredients and found to be present in any sample of the product (standard certified limits cannot be used for impurities). Certified limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production. The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85). Chevron has responded to the Guidance Document for both of its 90% Ts. However, these CSFs do not provide nominal concentrations for two impurities which are themselves active ingredients, and a nominal concentration was not provided for the active ingredient, naled; these data are required. New information should be submitted on EPA Form 8570-4 (Rev. 2/85). In addition, the CSFs for the Chevron 90% Ts identify the formulations as alternate; if these represent an alternate formulation, the registrant should identify the basic formulation and submit

TABLE B. (Continued).

pertinent product chemistry data. DEB has determined that data are available to satisfy this requirement for the AMVAC 90% T (J. Garbus, DEB No. 1197, 10/16/85).

9. No data have been submitted by Valent for their product listed in Footnote 1. The registrants must submit analytical methods which are suitable for enforcement purposes for each active ingredient and each additional ingredient or impurity that is determined to be toxicologically significant. Suitability for enforcement purposes shall be determined from validation studies of method accuracy and precision submitted by the registrant. Chevron has responded to the Guidance Document. The submitted data are adequate for the Chevron and AMVAC 90% Ts.

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

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11. As per the Guidance Document, the Chevron products have submitted adequate data for this topic; these data apply to the AMVAC 90% T also. Valent has not submitted data pertaining to their product listed in Footnote 1 and must address this data requirement.

12. No data have been submitted on this topic by Valent for their products listed in Footnote 1, or by Chevron for the 90% T (EPA Reg. No. 62499-14). For these products, this data requirement must be fulfilled. If Chevron provides documentation that their two 90% Ts are the same TGAI, additional data for EPA Reg. No. 62499-14 may not be required. Chevron has responded to the Guidance Document for the 90% T (EPA Reg. No. 62499-38); the data submitted are adequate for this topic for the Chevron 90% T (EPA Reg. No. 62499-38) and the AMVAC 90% T (EPA Reg. No. 5481-198).

13. No data have been submitted by Amvac, Valent, and Chevron for their products listed in Footnote 1. Data are required on flammability if the product contains combustible liquids.

14. Data are required if the product is potentially explosive.

TABLE B. (Continued).

15. Data on viscosity are required if the product is a liquid.

16. Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

NALED

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

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

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

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NALED SH. # 034401

Page_____ is not included in this copy.

Pages 21 through 31 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.

X CONFIDENTIAL APPENDICES

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

DYNAMAC
CORPORATION

Final Report

6/8/90

NALED
Task 4: Residue Chemistry Registration Standard Update

Contract No. 68-D8-0080

MAY 7, 1990

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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

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NALED

REGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 4

Table of Contents

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NALED

REGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 4

INTRODUCTION

The 5/2/89 update of the Index of Pesticide Chemicals identifies registered food/feed uses for the insecticide Naled (1,2-dibromo-2,2-dichloro-ethyl dimethyl phosphate) on the following crops: alfalfa, almonds, beans (succulent and dried), broccoli, Brussels sprouts, cabbage, cauliflower, celery, chard, collards, cotton, cucumbers, eggplants, grapes, grapefruit, hops, kale, lemons, lettuce, melons, mushrooms, oranges, pasture grasses, peas, peaches, peppers, pumpkins, rice, safflower, soybeans, spinach, squash, strawberries, sugar beets, tangerines, tobacco, tomatoes, and walnuts. Naled formulations variously registered for foliar, dormant and delayed dormant use on food/feed crops (except mushrooms) include the 4% dust (D), the 4 and 8 lb/gal, and the 58% emulsifiable concentrate (EC), 14 lb/gal and 20% soluble concentrate/liquid (SC/L). The 8 lb/gal EC and the 10% RTU are registered for vapor, fog, or aerosol application to mushrooms. The 10 and 15% ready-to-use (RTU) formulations are registered for greenhouse treatment of tomatoes and outdoor application to pastures, respectively. Naled is also registered for use on animal buildings and premises (4% D, 4 and 8 lb/gal EC, 14 lb/gal and 20% SC/L), poultry houses (4 lb/gal EC) and as a spray treatment for poultry (4 lb/gal EC).

Note to SSRD: The data gaps which appear in this update are based on the assumption that the use patterns for naled have not changed since the 5/2/89 update of the Index of Pesticide Chemicals. Although the major registrant has indicated that several uses will be removed from its labels, products remain registered by other companies for similar uses.

The Naled Guidance Document dated June, 1983 identifies outstanding data gaps for plant and animal metabolism, residue analytical methods, storage stability, and the magnitude of the residue in alfalfa, beans (seeds and foliage), broccoli, Brussels sprouts, cabbage, cauliflower, celery, chard, collards, cotton, cucumbers, eggplants, grapes, oranges, grapefruit, grass forage, hops, kale, lemons, lettuce, melons, mushrooms, peas (seed and foliage), peaches, peppers, pumpkins, rice grain, soybeans (seed and foliage), spinach, squash (summer and winter), strawberries, tangerines, tomatoes, turnips (roots and tops), and in eggs and poultry. In addition, data are needed pertaining to the magnitude of the residue in tobacco. In response to the Guidance Document, Chevron Chemical Company has submitted data pertaining to plant metabolism (MRIDs 00151525 and 00154126), animal

metabolism (MRIDs 00126462, 00126463, 00154122, and 00154129), residue analytical methods (MRIDs 00160765 and 40506401), storage stability (MRID 00160765), and the magnitude of the residue in plants (MRIDs 00154126, 00160765, 40376601, 40407301, 40506401, 40605201, and 40633601). The available data, up to 3/5/90, have been reviewed by the Agency or are otherwise reviewed in this update (MRIDs 00160765 and 40605201) for their adequacy in fulfilling the outstanding data requirements.

Tolerances for residues of naled in or on raw agricultural commodities and animal products are currently expressed in terms of the combined residues of naled and its metabolite 2,2-dichlorovinyl dimethyl phosphate (DDVP), calculated as naled equivalents (40 CFR §180.215).

A tolerance of 0.5 ppm is established for naled in or on all raw agricultural commodities, except those otherwise listed in the 40 CFR 180.215 section, from use of the pesticide for area pest (mosquito and fly) control (40 CFR 180.215).

SUMMARY

The following Naled Residue Chemistry data are required:

- Additional data pertaining to the qualitative nature of the residue in poultry (dermal exposure).
- A revised version of the residue analytical method RM-3G-4, which eliminates the recommendation for a particular brand of acetonitrile.
- 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. Data are required which depict the decline in levels of DDVP in commodities stored under the range of conditions and for the range of intervals specified.
- Data depicting naled residues of concern in or on alfalfa hay, broccoli, Brussels sprouts, beans, cabbage, cauliflower, celery, collards, cottonseed, cucumbers, eggplant, grass forage and hay, hops, kale, lettuce, melons, mushrooms, peaches, pea vines and hay, peppers, pumpkins, soybeans, soybean forage and hay, spinach, summer squash, Swiss chard, strawberries, tomatoes, and tobacco following registered uses.

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QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The Naled Guidance Document dated June, 1983 concludes that the qualitative nature of the residue in plants is not adequately delineated and requires additional data on the identity and amount (if any) of organic brominated components of the residue in plants.

Since the issuance of the Guidance Document, Chevron Chemical Company submitted data (MRIDs 00151525 and 00154126) pertaining to the metabolism of naled in plants (processed oranges and tomatoes). These data were reviewed in Addendum #1 to the Naled Residue Chemistry Chapter and judged adequate to fulfill data requirements; in the cover memorandum for the Addendum, C.L. Trichilo (DEB No. 160, 2/6/86) notes that Toxicology Branch concludes that no data are required at the present time pertaining to organic brominated components which may be present in plants as a result of the metabolism or breakdown process of naled per se and/or its manufacturing impurities.

Naled is hydrolyzed to dimethylphosphate and dibromodichloro-acetaldehyde (BDCA) and/or debrominated in the presence of sulfhydryl compounds to form DDVP, which may evaporate from leaf surfaces under field conditions. DDVP remaining in or on the plant is subject to hydrolysis, forming dimethylphosphate and dichlorovinylalcohol. Dichlorovinylalcohol is converted to dichloroethanol which is then conjugated and/or incorporated into naturally occurring plant components. The dimethylphosphate component of hydrolyzed naled is sequentially degraded to monomethyl phosphate and inorganic phosphates.

References (used):

MRID(s): 00154126.

References (not used):

[The following reference(s) contains a summary of data in MRID 00154126 and other, previously reviewed data.]

MRID(s): 00151525.

Discussion of the data:

N/A.

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data on the identity and amount (if any) of organic brominated components of the residue derived from naled itself or from its bromine-containing impurities in animals.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRIDs 00126462 and 00126463) which were reviewed by G.P. Makhijani (EPA Memorandum dated 9/27/84) and in Addendum #1 to the Naled Residue Chemistry Chapter, and judged adequate to fulfill data requirements; in the cover memorandum for the Addendum, C.L. Trichilo (DEB No. 160, 2/6/86) notes that Toxicology Branch concludes that no data are required at the present time pertaining to organic brominated components in animals which may be present as a result of the metabolism or breakdown process of naled per se and/or its manufacturing impurities.

The Index dated 5/2/89 lists direct uses of naled on poultry, and no metabolism studies pertaining to these uses are available. Therefore, the following additional data are required.

- A metabolism study in which laying hens receive direct applications of ethyl-[^{14}C]naled in a manner representative of registered uses. Animals must be treated at a concentration that will result in sufficient residues in the tissues for characterization. Animals must be sacrificed 24 hours after treatment and residues characterized in muscle, fat, liver, and eggs.

The metabolic pathway in ruminants and poultry following oral exposure involves debromination of naled to form DDVP, which is hydrolysed to dichloroacetaldehyde (DCA). A small part of the DDVP also undergoes O-demethylation to form desmethyl-DDVP. In part, DCA is reduced to dichloroethanol which is conjugated with endogenous sulfate to form the sulfate ester conjugate of dichloroethanol, the major metabolite resulting from oral ingestion in poultry. The major naled metabolite in goat tissue and excreta is the glucuronidate conjugate of dichloroethanol. The remaining DCA (and perhaps some of the dichloroethanol) is de-chlorinated to glyoxylic acid, which incorporates into common metabolic pathways (protein, lipid, and carbohydrate synthesis). The only residues of organic brominated compounds resulting from the metabolism of naled itself are parent compound and BDCA, both of which are very rapidly debrominated by sulfhydryl compounds or by hydrolysis. The residues of concern resulting from oral exposure in ruminants and poultry are naled per se, and its metabolite DDVP.

References (used):

MRID(s): 00126462. 00126463.

References (not used):

[The following reference(s) duplicate data in MRID 00126462.]

MRID(s): 00154122. 00154129.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Adequate methodology is available for enforcement of tolerances for the combined residues of naled and DDVP. The Naled Guidance Document dated June, 1983 requires additional data on analytical methodology and on residues of naled and DDVP determined separately for two representative crops such as lettuce and rice grain.

Gas-liquid chromatographic (GLC) methods are available for residues of naled and its metabolite DDVP in animal tissues, crops, and milk using a thermionic detector (Method RM-3G) and in fruits and vegetables using a GLC/microcoulometric method (Method RM-3C), both included in PAM, Volume II, Sec. 180.125, as Method I and Method A, respectively. In addition, the Naled Residue Chemistry Chapter dated 6/8/83 cited a number of analytical methods developed or adapted for determination of naled and DDVP in raw agricultural commodities. Methods RM-3, RM-3A, and RM-3E are cholinesterase inhibition methods and methods RM-3G, RM-3G-3, and the method of Boone are GLC methods using thermionic detectors for separate determination of naled and DDVP. Method RM-3G has undergone a successful FDA method validation on milk in conjunction with PP#1F1111 at fortification levels of 0.01 and 0.05 ppm (D. Edwards, no DEB No. dated 4/21/88).

Chevron Chemical Company submitted method RM-3G-4 (MRIDs 00160765 and 40506401) for determination of naled and DDVP residues in crops; the submission was reviewed by DEB (E.T. Haeberer, dated 1/10/90; no DEB No.) who concludes that the method is adequate for enforcement of tolerances for residues in almonds, broccoli, oranges, and alfalfa. Method RM-3G-4 is a revision of Method RM-3G-3 with modifications to the cleanup steps and updated instrument conditions, using a nitrogen-phosphorous detector (the limit of detection for both compounds is 0.01 ppm). It is recommended that the registrant submit a revised version of this

method which eliminates the recommendation for a specific brand of acetonitrile and that the registrant confirm that the calculation of residue levels reflects the total residues of naled and its metabolite DDVP (calculated as equivalents of naled). The following additional data are required:

- O A revised version of the residue analytical method RM-3G-4 which eliminates the recommendation for a particular brand of acetonitrile should be submitted. The registrant should confirm if the calculation of residue level is to reflect the total residues of naled and its metabolite DDVP (calculated as equivalents of naled).

Naled is partially recovered using FDA Multiresidue method 232.3 and completely recovered using Protocol D (with special GLC/HPLC); naled is not recovered using FDA Multiresidue Protocol E, and DDVP has been targeted for study using Protocols A and D (information pertaining to FDA Multiresidue Protocols is located in the Pestrak data base, PAM Vol. I, Addendum dated 12/13/89).

References (used):

MRID(s): 00160765. 40506401.

Discussion of the data:

N/A.

STORAGE STABILITY DATA

The Naled Guidance Document dated June, 1983 requires additional data depicting storage stability to indicate a potential for the loss of residues between sampling and analysis.

Data submitted by Chevron Chemical Company (MRID 00160765) pertaining to the stability of residues in beans, celery, citrus, peas, and strawberries were reviewed by L. Cheng (DEB No. 1931, dated 3/30/87). It was concluded that adequate storage stability data are available for residues in hexane extracts only; naled and DDVP were stable in hexane extracts of treated beans, peas, and citrus stored at 4°C for ca. 9 months. However, available data indicate that residues of naled in oranges and strawberries stored under frozen conditions (-20 C) remained stable for 1 month, but by the end of 6 months, naled residues can convert to DDVP. These data also indicated that while DDVP residues increased by 50% on treated oranges, these residues decreased by 13% in or on treated strawberries stored at ca. -20 C for 6 months.

The Agency requires that storage intervals and sample storage conditions be reported for all residue data submitted in support

of tolerances or otherwise required by the Agency, and that the residue data be accompanied by data depicting the stability of all residues of concern in storage (Pesticide Assessment Guidelines, Subdivision O). Therefore, 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 data in support of previously submitted residue data are required only for those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of naled and its metabolite DDVP in commodities stored under the range of conditions and for the range of intervals specified. Crop samples bearing measurable weathered residues or fortified with naled and DDVP 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 metabolite 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.

References (used):

MRID(s): 00160765.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN PLANTS

The Naled Guidance Document dated June, 1983 identifies field residue data requirements for alfalfa, beans (seeds and foliage), broccoli, Brussels sprouts, cabbage, cauliflower, celery, chard, collards, cotton, cucumbers, eggplants, grapes, oranges, grapefruit, grass forage, hops, kale, lemons, lettuce, melons, mushrooms, peas (seed and foliage), peaches, peppers, pumpkins, rice grain, soybeans (seed and foliage), spinach, squash, strawberries, tangerines, tomatoes, and turnips (roots and tops). Also, processing studies are required for cottonseed, grapes, hops, oranges, rice, soybeans, and tomatoes. Data were not required for tobacco in the Guidance Document; however, due to

evolving Agency policies regarding requirements for residue chemistry data, they are being required at this time. No data have been submitted pertaining to Brussels sprouts, chard (Swiss), cucumbers, eggplants, kale, lettuce, melons, mushrooms, peaches, peppers, pumpkins, rice grain, soybeans, spinach, squash, tangerines, tobacco, tomatoes, or turnips (roots and tops), or concerning processing of cottonseed, grapes, hops, rice, or soybeans.

Leafy Vegetables Group

Celery

Tolerance(s):

A tolerance of 3 ppm has been established for the combined residues of naled and its metabolite DDVP in or on celery [40 CFR §180.215].

Use directions and limitations:

The 4% D and the 8 lb/gal and 58% EC formulations are registered for multiple foliar applications to celery at 2 and 1.35 lbs ai/A, respectively, with ground and aerial equipment. A 4-day PHI has been established. Use of the 6% D formulation in celery has been cancelled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data reflecting five or more ground applications of an EC at 1.35 lb ai/A, and five or more ground and aerial applications of the 4 or 6% D at 2 lb ai/A.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on celery. The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 3 ppm in or on celery harvested 1 day after the last of five applications of the EC formulation. However, no data were submitted reflecting applications of a D formulation. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or celery harvested 4 days after the last of five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA(72%) and FL(20%), since these states accounted for ca. 92% of the 1986 U.S.

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celery production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87, p. 8).

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from two tests conducted in CA and FL pertaining to residues of naled and its metabolite DDVP in or on celery. Combined residues (expressed as naled) were 0.29-0.88 ppm in or on four untrimmed samples and 0.12-0.63 ppm in or on four trimmed samples harvested 1 day following the last of five ground applications of the 58% EC formulation at 1.35 lb ai/A (1x the maximum registered rate). Apparent residues in or on four untreated control samples were <0.02(nondetectable)-0.02 ppm. Residue data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector (limit of detection was 0.01 ppm for each compound). Recoveries of naled were 76-92% and for DDVP were 75-107%, from eight samples fortified with each compound at 0.1 ppm. Whole samples were shipped frozen and after extraction were stored frozen (-20 C) for ca. 6-412 days prior to analysis.

Geographic representation for celery is adequate since the test states of CA(72%) and FL(20%) collectively accounting for ca. 92% of the 1986 celery production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87, p. 8). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 3 ppm for residues in or on celery treated with the EC formulation. However, no data were submitted reflecting use of the 4% D formulation. Additional data are required.

which has the highest percent ai?

Brassica Leafy Vegetables Group

Broccoli

Tolerance(s):

A tolerance of 1 ppm has been established for the combined residues of naled and its metabolite DDVP in or on broccoli [40 CFR §180.215].

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Use directions and limitations:

The 4% D and the 8 lb/gal and 58% EC formulations are registered for multiple foliar applications to broccoli at 2 and 1.35 lbs ai/A, respectively, with ground and aerial equipment. A 1-day PHI has been established. Use of the 6% D formulation on broccoli has been cancelled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data reflecting five or more applications, made with aerial and ground equipment, using the 4 or 6% D at 2 lb ai/A and an EC formulation at 1.8 lb ai/A.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on broccoli. The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 1 ppm after the last of four applications of the EC formulation using aerial and ground equipment. However, no data were submitted reflecting ground and aerial applications of a D formulation. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or broccoli harvested 1 day after the last of five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA since this state accounted for ca. 90% of the 1986 U.S. broccoli production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1987 Summary, 6/87, p. 20).

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from two tests conducted in CA pertaining to residues of naled and its metabolite DDVP in or on broccoli. Combined residues (expressed as naled) were <0.02 ppm (nondetectable) in or on each of two samples treated with aerial equipment and <0.09 ppm in or on each of two samples treated with ground equipment harvested 1 day following the last of four applications of the 58% EC formulation at 1.8 lb ai/A (1.3x the maximum registered rate). Apparent combined residues in or on two untreated control samples of broccoli were <0.02 ppm (nondetectable). Residues were collected using a GLC method (RM-3G-4) with a nitrogen-

phosphorous detector (limit of detection was 0.01 ppm for each compound). Recoveries of naled and DDVP were 87-90% and 73-84%, respectively, from four samples fortified with each compound at 0.1 ppm. Whole samples were shipped frozen and extracted samples were stored frozen (-20 C) for ca. 388-429 days prior to analysis.

Geographic representation for broccoli is adequate since CA accounted for ca. 90% of the 1986 U.S. broccoli production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87, p. 20). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 1 ppm in or on broccoli treated using the EC formulation. However, no data were submitted reflecting registered use of a D formulation. Additional data are required.

Cabbage

Tolerance(s):

A tolerance of 1 ppm has been established for the combined residues of naled and its metabolite DDVP in or on cabbage [40 CFR §180.215].

Use directions and limitations:

The 4% D and the 8 lb/gal and 58% EC formulations are registered for multiple foliar applications to cabbage at 2 and 1.35 lbs ai/A, respectively, with ground and aerial equipment. A 1-day PHI has been established. Use of the 6% D formulation in cabbage has been cancelled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional residue data reflecting five or more seasonal applications of the 4 or 6% D at 2 lb ai/A and of the EC formulation at 1.8 lb ai/A, with aerial and ground equipment.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on cabbage. The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 1 ppm in or on samples treated with the EC formulation using ground equipment. However, no data were submitted reflecting aerial applications of a representative EC formulation and ground or aerial applications of a D formulation. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or cabbage

harvested 1 day after the last of five or more aerial applications reflecting the maximum registered use of a representative EC and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA(8%), FL(16%), NY(15%), NC(5%), TX(16%), and WI(9%) since these states accounted for ca. 70% of the 1982 U.S. cabbage production (1982 Census of Agriculture, Vol. 1 Part 51, p. 338).

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from one test conducted in WI pertaining to residues of naled and its metabolite DDVP in or on cabbage. Combined residues (expressed as naled) were <0.03-<0.08 ppm in on or two samples of cabbage heads harvested one day following the last of five ground applications of the 58% EC formulation at 1.8 lb ai/A (1.3x the maximum registered use rate). Apparent combined residues in or on one untreated control sample were <0.02 ppm. Data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector (limit of detection was 0.01 ppm for each compound). Recoveries of naled and DDVP were 110 and 101%, respectively, from two samples fortified with each compound at 0.1 ppm. After extraction, samples were stored frozen (-20 C) for ca. 273 days prior to analysis.

Geographic representation for cabbage is inadequate since the test state of WI collectively accounted for only ca. 10% of the 1982 U.S. cabbage production (1982 Census of Agriculture, Vol. 1, Part 51, p. 338). The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 1 ppm in or on samples treated with the EC formulation using ground equipment. However, no data were submitted reflecting aerial applications of a representative EC formulation and ground and aerial applications of a D formulation. Additional data are required.

Cauliflower

Tolerance(s):

A tolerance of 1 ppm has been established for the combined residues of naled and its metabolite DDVP in or on cauliflower [40 CFR §180.215].

Use directions and limitations:

The 4% D and the 8 lb/gal and 58% EC formulations are registered for multiple foliar applications to cauliflower at 2 and 1.35 lbs ai/A, respectively, with ground and aerial equipment. A 1-day PHI has been established. Use of the 6% D formulation in cauliflower has been cancelled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data reflecting five or more seasonal applications of the 4 or 6% D at 2.0 lb ai/A and an EC formulation at 1.8 lb ai/A, with aerial and ground equipment.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or cauliflower. The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 1 ppm in or on cauliflower harvested 1 day after the last of four applications of the EC formulation using ground equipment. However, no data were submitted reflecting aerial applications of a representative EC formulation and ground or aerial applications of a D formulation. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or cauliflower harvested 1 day after the last of five or more aerial applications reflecting the maximum registered use of a representative EC formulation and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA since this state accounted for ca. 77% of the 1986 cauliflower production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87, p. 22).

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from one test conducted in FL pertaining to residues of naled and its metabolite DDVP in or on cauliflower. Combined residues (expressed as naled) were <0.03-<0.05 ppm in on or two samples of untrimmed whole heads and <0.02-0.05 ppm in or two samples of trimmed whole heads harvested one day following the last of four ground applications of the 58% EC formulation at 1.8 lb ai/A (1.3x the maximum registered use rate). Apparent residues in or

on two untreated control samples of trimmed and untrimmed cauliflower heads were <0.02 ppm (nondetectable). Residue data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector (limit of detection is 0.01 ppm for each compound). Recoveries of naled and DDVP were 83-95% and 78-96%, respectively, from four samples fortified with each compound at 0.05 ppm. After extraction, samples were stored frozen at -20 C for ca. 399 days prior to analysis.

Geographic representation for cauliflower is inadequate since the test state of FL accounted for <1% of the I986 U.S. cauliflower production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87, p. 22). The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 1 ppm for residues in or on cauliflower treated with the EC formulation using ground equipment. However, no data were submitted reflecting aerial applications of a representative EC formulation and ground and aerial applications of a D formulation. Additional data are required.

Collards

Tolerance(s):

A tolerance of 3 ppm has been established for the combined residues of naled and its metabolite DDVP in or on collards [40 CFR §180.215].

Use directions and limitations:

The 4% D and the 8 lb/gal, and 58% EC formulations are registered for multiple foliar applications to collards at 2 and 1.35 lbs ai/A, respectively, with ground and aerial equipment. A 4-day PHI has been established. Use of the 6% D formulation in collards has been cancelled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data reflecting five or more seasonal applications of the 4 or 6% D at 2.0 lb ai/A and an EC formulation at 1.8 lb ai/A, with aerial and ground equipment.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on collards. The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 3 ppm in or on collards harvested 1 day after the last of five applications of the EC formulation using ground equipment. However, no data were

submitted reflecting aerial applications of a representative EC formulation and ground and aerial applications of a D formulation. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or collards harvested 4 days after the last of five or more aerial applications reflecting the maximum registered use of a representative EC formulation and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in AL(7%), FL(10%), GA(20%), NJ(6%), NC(6%), or SC(9%), and TX(8%) since these states accounted for ca. 66% of the 1982 U.S. collards production (1982 Census of Agriculture, Vol. 1, Part 51, p. 342).

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from one test conducted in FL pertaining to residues of naled and its metabolite DDVP in or on collards. Combined residues (expressed as naled) were <0.02 ppm (nondetectable) in on or two samples of mature green collards harvested one day following the last of five ground applications of the 58% EC formulation at 1.8 lb ai/A (1.3x the maximum registered use rate). Apparent residues in or on one untreated control sample were <0.02 ppm (nondetectable). Residue data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector (the limit of detection was 0.01 ppm for each compound). Recoveries of naled and DDVP were 111% and 82%, respectively, from two samples fortified with each compound at 0.10 ppm. After extraction, samples were stored frozen at -20 C for ca. 394 days prior to analysis.

Geographic representation for collards is inadequate since the test state of FL accounted for only 10% of the 1982 collards production (1982 Census of Agriculture, Vol. 1, Part 51, p. 342). The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of 3 ppm in on or green collards harvested 1 day after the last of five applications of the EC formulation using ground equipment. However, no data were submitted reflecting aerial applications of a representative EC formulation and ground and aerial applications of a D formulation. Additional data are required.

Legume Vegetables Group

Beans (succulent and dried)

Tolerance(s):

A tolerance of 0.5 ppm has been established for the combined residues of naled and its metabolite DDVP in or on beans (dried and succulent) [40 CFR §180.215].

Use directions and limitations:

The 4% D formulation is registered for use on beans (dried) at 2 lb ai/A. The 8 lb/gal EC is used at 1.35 lb ai/A on dried and succulent beans. Applications are made as needed with aerial or ground equipment. Treated vines are not to be fed to livestock. A PHI of 4 days is in effect.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional field residue data for beans reflecting three or more applications of an EC and the 4 or 6% D formulations during the fruiting period with aerial and ground equipment.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on lima and snap beans. The data were reviewed by L. Cheng (DEB No. 1931, 3/30/87), who concluded residues were below the tolerance in or on beans harvested 1 day following the last of multiple applications of the 58% EC formulation. However, no data were submitted reflecting applications of a D formulation. In addition, we note that data on cannery waste from treated beans are required. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in or on beans (dried) harvested 4 days after three or more ground and aerial applications during the fruiting period of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA(12%), ID(11%), MI(21%), NE(13%), and ND(19%) since these states accounted for ca. 76% of the 1987 U.S. dry beans production (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988).

- Data are required depicting residues in cannery residue prepared from beans bearing measurable weathered residues. If residues concentrate in this feed item, an appropriate feed additive tolerance must be proposed.

References (used):

MRID(s): 00160765.

Discussion of the data:

N/A.

Peas (succulent and dried)

Tolerance(s):

A tolerance of 0.5 ppm has been established for the combined residues of naled and its metabolite DDVP in peas (succulent) [40 CFR §180.215].

Use directions and limitations:

The 8 lb/gal EC formulation is registered for multiple aerial and ground applications to peas at 1.35 lb ai/A. A PHI of 4 days is in effect. Use of the 4% D formulation in peas has been canceled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional field residue data for peas reflecting three applications during the fruiting period of the 4% D and an EC formulation at the maximum rates using aerial and ground equipment. Dried, succulent, and edible-pod types must be included.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on peas. The data were reviewed by L. Cheng (DEB No. 1931, 3/30/87), who concluded residues were below the tolerance in or on peas harvested 1 day following the last of multiple applications of the 58% EC formulation. No additional data are required.

References (used):

MRID(s): 00160765.

Discussion of the data:

N/A.

Foliage of Legume Vegetables Group

Pea vines and hay

Tolerance(s):

A tolerance of 10 ppm has been established for the combined residues of naled and its metabolite DDVP in or on forage legumes [40 CFR §180.215].

Note to SRRD: Concomitant with the establishment of individual tolerances for naled residues in or on pea vines and hay, the 40 CFR entry for legumes, forage should be deleted.

Use directions and limitations:

The 8 lb/gal EC formulation at 1.35 lb ai/A of naled is registered for aerial and ground use on peas. A PHI of 4 days is in effect. The 4% dust formulation registration use has been canceled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional field residue data for peas reflecting three applications of the 4% D and an EC formulations at the maximum registered rates during the fruiting period with aerial and ground equipment.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on pea vines. The data were reviewed by L. Cheng (DEB No. 1931, 3/30/87), who concluded residues were below the tolerance in or on pea vines harvested 1 day following the last of multiple applications of the 58% EC formulation. No additional data are required; however, individual tolerances are needed for pea vines and hay.

References (used):

MRID(s): 00160765.

Discussion of the data:

N/A.

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Citrus Fruits Group

Tolerances of 3 ppm have been established for the combined residues of naled and DDVP in or on grapefruits, lemons, oranges, and tangerines [40 CFR 180.215].

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data to support the established tolerances for residues in or on grapefruits, lemons, oranges, and tangerines. Data in or on lemons and oranges are requested reflecting 10 aerial and ground application of the 4% D and an EC formulation at 4 and 1.8 lb ai/A, respectively; five or more of these application must be made during the fruiting period. Data are also needed on processed orange products, cold pressed oil, peel, dehydrated pulp and molasses. In response to the Guidance Document, Chevron Chemical Company submitted data (MRIDs 00160765 and 40376601) which were reviewed by DEB (L. Cheng, EPA Memorandum DEB No. 1931, dated 3/30/87) who concludes that the available data indicate residue levels were lower than the established tolerances (3 ppm) in or on oranges, lemons, and grapefruit, provided the number of application is limited to four. The following additional data are required:

- A processing study depicting residues of naled and its metabolite DDVP in dried pulp, oil, molasses, and juice processed from citrus fruit bearing measurable weathered residues is required. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

References (used):

MRID(s): 00160765. 40376601.

Discussion of the data:

N/A.

Small Fruits and Berries Group

Grapes

Tolerance(s):

A tolerance of 0.5 ppm has been established for the combined residues of naled and its metabolite DDVP in or on grapes [40 CFR §180.215].

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Use directions and limitations:

The 4% D and the 8 lb/gal and 58% EC formulations are registered for multiple foliar applications to grapes at 2 and 1.35 lbs ai/A, respectively, with ground and aerial equipment. A 4-day PHI has been established.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional residue data reflecting 10 aerial and ground applications of the 4% D at 2.0 lb ai/A and data pertaining to naled residues in grape products (juice, wet and dehydrated pomace, raisins, and raisin waste) are needed to determine if food additive tolerances should be established for these products.

In response to the Guidance Document, the registrant submitted data pertaining to residues of naled and its metabolite DDVP in or on grapes (MRID 00160765). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 0.5 ppm following treatment with the 58% EC and 4% D formulations. However, no data were submitted pertaining to naled residues in grape processed commodities (juice, wet and dry pomace, raisins, and raisin waste). The following additional data are required:

- A processing study depicting residues of naled and its metabolite DDVP (expressed as naled) in wet and dry pomace, raisins, raisin waste, and juice processed from grapes bearing measurable weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from two tests conducted in CA pertaining to residues of naled and its metabolite DDVP in or on grapes. Combined residues (expressed as naled) were <0.02 ppm (nondetectable) in or on four samples of mature bunches harvested four days following the last of six ground and aerial applications of the 4% D and 58% EC formulations at 2 lb ai/A (1x the maximum registered use rate). Apparent residues in or on two untreated control samples were <0.02 ppm (nondetectable). Data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector (limit of detection is 0.01 ppm for each compound). Recoveries of naled

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and DDVP were 79-88% and 79-81%, respectively from four samples fortified with each compound at 0.10 ppm. After extraction, samples were stored frozen (-20 C) for ca. 27-43 days prior to analysis.

Geographic representation for grapes is adequate since the test state of CA accounted for 89% of the 1987 U.S. grape production (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 0.5 ppm in or on grapes treated with the EC formulation. However, no data were submitted pertaining to naled residues in grape processed commodities (juice, wet and dry pomace, raisins, and raisin waste). Additional data are required.

Strawberries

Tolerance(s):

A tolerance of 1 ppm has been established for the combined residues of naled and its metabolite DDVP in or on strawberries [40 CFR §180.215].

Use directions and limitations:

The 4% D and the 8 lb/gal (equivalent to 7.2 lb/gal naled) or 58% EC formulations are registered at 2 and 0.9 lbs ai/A, respectively, for multiple dormant and foliar applications to strawberries with ground and aerial equipment. A 1-day PHI has been established. Use of the 6% D formulation in strawberries has been cancelled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional residue data reflecting five aerial and ground applications of the 4 or 6% D at 2.0 lb ai/A and an EC formulation at 0.9 lb ai/A.

In response to the Guidance Document, the registrant submitted data pertaining to residues of naled and its metabolite DDVP in or on strawberries (MRID 00160765). The available data indicate that combined residues were below the established tolerance of 1 ppm in or on strawberries harvested 0-1 day after the last of five ground applications of the EC formulation. However, no data were submitted reflecting aerial applications of a representative EC formulation and ground and aerial applications of a D formulation. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or strawberries harvested one day after the last of five or

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more aerial applications reflecting the maximum registered use of a representative EC formulation and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA since this state accounted for ca. 77% of the 1986 strawberries production (Vegetables, 1986 Summary Ag. Statistics Board, NASS, USDA, 6/1987, p. 27).

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from two tests conducted in CA(1) and OR(1) pertaining to residues of naled and its metabolite DDVP in or on strawberries. Combined residues (expressed as naled) were 0.24-1.1 ppm in or on four samples of mature fruits harvested 0-1 day following the last of five ground applications of the 58% EC formulation at 0.9 lb ai/A (1x the maximum registered use rate). Apparent residues in or on two untreated control samples were <0.02 ppm (nondetectable). Data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector (limit of detection is 0.01 ppm for each compound). Recoveries of naled and DDVP were 78-119% and 73-80%, respectively, from four samples fortified with each compound at 0.1 ppm. After extraction, samples were stored frozen (-20 C) for ca. 109-139 days prior to analysis.

Geographic representation for strawberries is adequate since the test states of CA(77%) and OR(6%) accounted for ca. 83% of the 1986 strawberries production (Vegetables, 1986 Summary Ag. Statistics Board, NASS, USDA, 6/1987, p. 27). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 1 ppm in or on strawberries treated with the EC formulation. However, no data were submitted reflecting aerial applications of a representative EC formulation and ground and aerial applications of the 4% D formulation. Additional data are required.

Grass, Forage, Fodder, and Hay Group

Grass (pasture and rangeland)

Tolerance(s):

A tolerance of 10 ppm has been established for the combined residues of naled and its metabolite DDVP in or on grass forage [40 CFR §180.215].

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Use directions and limitations:

The 4% D, the 8 lb/gal, and 58% EC, and the 14 lb/gal SC/L formulations are registered for foliar applications to grass pastures and rangeland with ground and aerial equipment. A 1-day PHI has been established. Use of the 6% D formulation in grass forage has been cancelled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires residue data for grass reflecting five aerial and ground applications of the 4% D at 0.4 lb ai/A and residue data for grass hay are needed to determine if a separate, or increased tolerance should be established for this commodity.

In response to the Guidance Document, the registrant submitted data pertaining to residues of naled and its metabolite DDVP in or on grass forage (MRID 00160765). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 10 ppm in or on samples treated using the EC formulation. However, no data were submitted following the last of five aerial and ground applications reflecting the maximum registered use of the 4% D formulation. In addition, no residue data for grass hay have been submitted. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or grass forage and hay harvested one day after the last of five aerial or ground applications reflecting the maximum registered use of the 4% D formulation. Tests must be conducted in AR(3%), GA(3%), KS(4%), KY(5%), MO(11%), NY(5%), OH(3%), OK(4%), OR(4%), PA(4%), SD(2%), TN(4%), TX(13%), VA(3%), and WI(2%) which collectively accounted for ca. 70% of the 1982 tame hay production (1982 Census of Agriculture, Vol.1, Part 51, p. 330).

- Data depicting residues of naled and its metabolite DDVP (expressed as naled) in or on grass hay to determine if a separate, or increased tolerance should be established for this commodity.

References (used):

MRID(s): 00160765.

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Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from three tests conducted in CO(1) and NY(2) pertaining to residues of naled and its metabolite DDVP in or on grass forage. Combined residues of naled and its metabolite DDVP (expressed as naled) were 1.4-7.7 ppm in or on six samples harvested 1-24 hours and 0.53-0.75 ppm in or on two samples harvested 48 hours following one aerial application of the 14 lb/gal SC/L formulation at 0.4 lb ai/A (0.5x the maximum registered use rate). Combined residues (expressed as naled) were <0.02(nondetectable)-5.2 ppm in or on twelve samples harvested 1-24 hours and <0.02 ppm (nondetectable) in or on four samples harvested 48 hours following five aerial applications of the 8 lb/gal EC formulation at 0.9 lb ai/A (1x the maximum registered use rate). Apparent residues in or on three untreated control samples of grass forage were <0.02 ppm (nondetectable). Data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector (limit of detection is 0.01 ppm for each compound). Recoveries of naled and DDVP were 60-90% and 75-95%, respectively, from 16 samples fortified with each compound at 0.1-0.2 ppm. After extraction, samples were stored frozen (-20 C) for ca. 144-386 days prior to analysis.

Geographic representation for grass forage is adequate since the test states of CO(1%) and NY(5%) representing the southwestern and northeastern regions, respectively, collectively accounted for 60% of the 1982 tame hay production, assuming CO represents the states of KS(4%), MO(11%), NE(1%), OK(4%), TX(13%), and WY(1%), and NY represents the states of IL(1%), IN(2%), IA(1%), MI(1%), MN(2%), OH(3%), PA(4%), VT(1%), VA(3%), and WI(2%) (1982 Census of Agriculture, Vol. 1, Part 51, p. 330). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 10 ppm for residues in or on grass forage treated with the EC formulation. However, no data were submitted reflecting aerial and ground applications of the 4% D formulation. In addition, no residue data for grass hay have been submitted to determine if a separate, or increased tolerance should be established. Additional data are required.

Non-grass Animal Feeds Group

Alfalfa forage and hay

Tolerance(s):

A general tolerance of 10 ppm has been established for the combined residues of naled and its metabolite DDVP in or on forage legumes [40 CFR §180.215].

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Use directions and limitations:

The 8 lb/gal and 58% EC formulations are registered for multiple foliar applications to alfalfa at 0.9 lb ai/A, with ground and aerial equipment. A 4-day PHI has been established. The use of the 4% D and SC/L formulations of naled in alfalfa have been canceled.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data for alfalfa forage reflecting five aerial and ground applications of the 4% D. Residue data are also required for alfalfa hay to determine if a separate tolerance should be established. Since the issuance of the Guidance Document, the use of naled in alfalfa has been amended; the use of the 4% D and SC/L formulations of naled in alfalfa have been deleted.

In support of a tolerance petition for residues of naled and its metabolite DDVP in alfalfa, Chevron Chemical Company has submitted data (1988; MRID 40605201) which indicate that residues of naled and its metabolite DDVP (expressed as naled) in or alfalfa forage and alfalfa hay will not exceed the established tolerance following aerial application of an EC formulation. The registrant must propose separate tolerances for residues of naled and its metabolite DDVP in or on alfalfa forage and alfalfa hay. In addition, no data have been submitted depicting residues of naled and its metabolite in or on alfalfa hay. The following additional data are required:

- Data depicting residues of naled and its metabolite DDVP (expressed as naled) in or on alfalfa hay harvested 4 days following the last of multiple aerial applications reflecting the maximum registered use of a representative EC formulation. Tests must be conducted in CA(9%), CO(3%), IA(6%), or ID(5%), or KS(4%), MI(4%), or MN(7%), NE(5%), ND(4%), OH(3%), PA(3%), SD(6%), WA(2%), and WI(9%) which collectively accounted for ca. 70% of the 1987 U.S. alfalfa grown for hay (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988).

- Individual tolerances must be proposed for residues in or on alfalfa forage and hay.

Note to SRRD: Concomitant with the establishment of an individual tolerance for naled residues in or on alfalfa forage and alfalfa hay, the 40 CFR 180.215 entry for "forage legumes" should be deleted.

References (used):

MRID(s): 40605201.

References (not used):

[The following reference(s) contains duplicate information from MRID 40605201.]

MRID(s): 00160765.

Discussion of the data:

[It should be noted that the raw agricultural commodities designated by the registrant as "fresh cut hay, mature green hay, and fresh forage" were interpreted as alfalfa forage; "alfalfa hay, hay, and cured hay" were interpreted as alfalfa hay.]

Chevron Chemical Company (1988; MRID 40605201) submitted data from six tests conducted in CA(2), IA(2), NJ(1), and WA(1) pertaining to residues of naled and its metabolite DDVP in or on alfalfa forage and alfalfa hay collected 1-4 days following the last of one to five broadcast ground applications of the 58% EC formulation at 1 to 2 lb ai/A (1.1-2.2x the maximum registered rate). Combined residues (expressed as naled) were <0.02 ppm (nondetectable) in or on two samples of alfalfa forage harvested 4 days following one application at 1.1x and were 0.26-0.79 ppm in or on eight samples harvested 1 day following three to five applications. Combined residues (expressed as naled) were <0.02 ppm (nondetectable) in or on six samples of alfalfa hay harvested 4 days following application at 1.1-2.2x. Apparent combined residues in or on three samples of alfalfa forage and two samples of alfalfa hay were <0.02 ppm (nondetectable). Data for both naled and its metabolite DDVP were collected using a GLC method (RM-3G) with a nitrogen-phosphorous detector (0.01 ppm limit of detection for each compound). Recoveries of naled were 57-77.3% from three samples of alfalfa forage and 72.2-78.9% from two samples of alfalfa hay fortified with naled at 0.201-0.208 ppm. Recoveries of DDVP were 75.5-108.1% from three samples of alfalfa forage and 77.1-94.9% from two samples of alfalfa hay fortified with DDVP at 0.051-0.104 ppm. Samples were stored frozen (-20 C) for ca. 6-23 days prior to analysis.

In the same submission, Chevron Chemical Company submitted data from two additional tests conducted in CA(1) and MO(1) pertaining to residues of naled and its metabolite DDVP in or on alfalfa forage and alfalfa hay collected immediately following the last of two broadcast ground applications of the 58% EC formulation at 0.81-0.9 lb ai/A (0.9-1x the maximum registered rate). Combined residues were <0.02 ppm (nondetectable) in or on two samples each

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of alfalfa forage and alfalfa hay harvested immediately following application at 0.9x. Two additional samples each of alfalfa forage and alfalfa hay harvested immediately following application at 1x bore 2.4-3.6 ppm and 0.12 ppm, respectively. Apparent combined residues in or on two untreated samples of alfalfa forage and two untreated samples of alfalfa hay were <0.02 ppm (nondetectable). Data were collected using a GLC method (RM-3G-4; modification of RM-3G) with a nitrogen-phosphorous detector (limit of detection was 0.01 ppm for each compound). Recoveries of naled were 61-77% from two samples of alfalfa forage and 88-98% from two samples of alfalfa hay fortified with naled at 0.1 ppm. Recoveries of DDVP were 62-91% from two samples of alfalfa forage and two samples of alfalfa hay fortified with DDVP at 0.1 ppm. Samples were stored frozen (-20 C) for ca. 229-405 days prior to analysis.

Geographic representation for alfalfa hay is adequate since the test states of CA(9%), IA(6%), MO(1%), NJ(<1%) and WA(2%) collectively accounted for ca. 65% of the 1987 U.S. alfalfa grown for hay, assuming neighboring states represent AR(1%), ID(5%), IL(3%), KS(4%), KY(1%), MN(7%), NE(5%), NV(1%), OK(2%), OR(2%), SD(6%), and WI(9%) (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988). The available data indicate that residues of naled and its metabolite DDVP will not exceed the tolerance in or on alfalfa forage and alfalfa hay, respectively treated with the EC formulation using ground equipment. The registrant must propose separate tolerances for residues of naled and its metabolite DDVP in or on alfalfa forage and alfalfa hay. In addition, no data have been submitted depicting residues of naled and DDVP in or on alfalfa hay harvested 4 days following the last of multiple aerial applications of a representative EC formulation at 0.9 lb ai/A. The registrant must propose separate tolerances for residues of naled and its metabolite DDVP in or on alfalfa forage and alfalfa hay.

Miscellaneous Commodities

Cottonseed

Tolerance(s):

A tolerance of 0.5 ppm has been established for the combined residues of naled and its metabolite DDVP in or on cottonseed [40 CFR §180.215].

Use directions and limitations:

The 4% D and the 8 lb/gal and 58% EC formulations are registered for multiple foliar applications to cotton at 1.4 and 0.9 lbs

ai/A, respectively, with ground and aerial equipment. A 4-day PHI has been established.

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional residue data reflecting five aerial or ground applications of the 4% D and an EC formulation at 1.4 and 0.9 lb ai/A, respectively. In addition, if residues were present in undelinted seed, then additional residue data (reflecting the above doses) for cottonseed hulls, meal, refined oil, and soapstock were required to determine if food additive tolerances should be established for these processed products.

In response to the Guidance Document, Chevron Chemical Company submitted data (MRID 00160765) pertaining to residues of naled and its metabolite DDVP in or on cottonseed. The available data indicate that combined residues of naled and its metabolite DDVP were below the established tolerance of.0.5 ppm in or on cottonseed harvested 65-106 days after the last of five applications of the EC formulation. However, no data were submitted reflecting ground and aerial applications of the 4% D formulation. In addition, no data were submitted pertaining to naled and DDVP residues in the following cottonseed processed commodities. The following additional data are required:

- Data depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or cottonseed harvested 4 days after the last of five ground and aerial applications of the 4% D formulation at 1.4 lb ai/A. Tests must be conducted in CA(20%), LA(7%), MS(12%), and TX(32%), since these states accounted for ca. 71% of the 1987 cotton production (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988).

- A processing study depicting residues of naled and its metabolite DDVP (expressed as naled) in meal, hulls, soapstock, crude oil, and refined oil from the processing of cottonseed bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

References (used):

MRID(s): 00160765.

Discussion of the data:

Chevron Chemical Company (1986; MRID 00160765) submitted data from three tests conducted in CA(2) and MS(1) pertaining to residues of naled and its metabolite DDVP in or on cottonseed.

Combined residues (expressed as naled) were <0.02(nondetectable)-0.04 ppm in on or six samples of fuzzy cottonseeds harvested 65-106 days following the last of five ground or aerial applications of the 58% EC formulation at 0.9 lb ai/A (1x the maximum registered use rate). Apparent residues in or on three untreated control samples were <0.02 ppm (nondetectable). Residue data were collected using a GLC method (RM-3G-4) with a nitrogen-phosphorous detector; the limit of detection was 0.01 ppm for each compound. Recoveries of naled and DDVP were 72-100% and 80-90%, respectively, from six samples fortified with each compound at 0.10 ppm. Samples were stored frozen (-20 C) for ca. 2-6 days before extraction and 1-38 days prior to analysis.

Geographic representation for cotton is adequate since the test states of CA(20%) and MS(12%) collectively accounting for ca. 74% of the 1988 cotton production, assuming MS represents the southwestern production region with AL(3%), LA(7%), and TX(32%) (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988). The available data indicate that combined residues of naled and its metabolite DDVP were below the tolerance of 0.5 ppm for residues in or on cottonseed treated with the EC formulation. However, no data were submitted reflecting ground and aerial applications of the 4% D formulation. In addition, no data were submitted pertaining to naled and DDVP residues in cottonseed processed commodities. Additional data are required.

Tobacco

The Naled Guidance Document required no data concerning the magnitude of the residue on tobacco. Although the use of a pesticide on tobacco does not require a tolerance or an exemption from the requirement to obtain a tolerance, data are needed to assess the exposure of man to the residue remaining at the time of use of the tobacco. Therefore, the following data are required:

- A residue profile in tobacco leaves following application of the EC formulation of ethyl-^{14}C-naled at the maximum registered use rate must be submitted. If total residues in or on green freshly-harvested tobacco are $\geq$ 0.1 ppm, then residues must be determined in cured or dried tobacco. If residues $\geq$ 0.1 ppm are detected, then pyrolysis products derived from the active ingredient must be characterized and the level of residue in smoke must be quantified.

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Wide Area and General Outdoor Treatments

Conclusions:

The Addendum to the Registration Standard dated 9/20/85 required data depicting residues of naled and DDVP in or on representative commodities from all crop groups listed in 40 CFR 180.34 following multiple aerial and, in separate tests, ground applications of an EC and SC/L formulation at 0.25 lb ai/A, in order to support the established tolerance for residues in or on raw agricultural commodities as a result of the use of naled for mosquito and fly control

In response, Chevron Chemical Company submitted data (1987: MRID 40407301; 1988; MRIDs 40506401 and 40633601) which were reviewed by D. Edwards and F.B. Suhre (EPA Memoranda DEB Nos. 3397-99 dated 4/5/88, and No 4009, dated 9/7/88, respectively) who conclude that the submitted data support the established tolerance. In addition, it was concluded that the fly and mosquito use restriction currently on naled labels which prohibits application over acreage containing certain crops may be removed.

References (used):

MRID(s): 40407301. 40506401. 40633601.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN ANIMALS

Milk and the Fat, Meat and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep

Conclusions:

The Naled Guidance Document dated June, 1983 concluded that the available data support the established tolerances for combined residues of naled and DDVP from dietary sources in the meat and milk of cattle. The data are considered supportive of the tolerances for residues in the meat and milk of other animals (goats, hogs, horses and sheep) as well.

Presently, data gaps exist concerning the magnitude of residues of naled and its metabolite DDVP in feed items of animals such as alfalfa (forage and hay), grass (forage and hay), cotton processed commodities (meal, hulls, and soapstock), turnip tops, and rice (grain and forage). Upon receipt of the field trials and processing data, the adequacy of tolerances for residues of

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naled and its metabolite DDVP (calculated as naled) in livestock will be reassessed, the expected dietary intake for beef cattle, dairy cattle, and swine will be calculated, and the need for additional feeding studies will be reevaluated.

References (used):

N/A.

Discussion of the data:

N/A.

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

Conclusions:

The Naled Guidance Document dated June, 1983 requires additional data on eggs and poultry resulting from 10 bird-spray treatments with either the 3.6 or 7.2 lb/gal EC at 0.45 lb ai/20 gal.

Since the issuance of the Guidance Document the use of the 8 lb/gal EC as a spray treatment for poultry has been cancelled. However, no data have been submitted by the registrant pertaining to residues of naled and its metabolite DDVP on eggs and poultry resulting from spray treatment with the 4 lb/gal EC formulation. Presently, data gaps also exist concerning poultry metabolism and the magnitude of residues in feed items of poultry such as alfalfa (seed and meal), cotton processed commodities (meal and soapstock), and rice (grain, milled byproducts, and grain dust). Upon receipt of the required metabolism, residue, and processing data, the expected dietary intake for poultry will be calculated, the adequacy of tolerances for residues of naled and its metabolite DDVP (calculated as naled) in poultry and eggs will be reassessed, and the need for additional feeding studies will be reevaluated.

References (used):

N/A.

Discussion of the data:

N/A.

MASTER RECORD IDENTIFICATION NUMBERS

Residue Chemistry Citations (used):

00126462 Cheng, H.; Tucker, B. (1983) Metabolic Fate of Naled in Chickens after a Single Oral Dose of (Ethyl-1-14C)-naled: File No. 721.14/Naled. (Unpublished study received Mar 9, 1983 under 239-1633; submitted by Chevron Chemical Co., Richmond, CA; CDL:249713-A)

00126463 Cheng, H.; Tucker, B. (1983) Characterization of 14C in Chicken Tissues and Eggs after Dosing with (Ethyl-1-14C)-Naled for 10 Consecutive Days: File No. 721.14/naled. (Unpublished study received Mar 9, 1983 under 239-1633; submitted by Chevron Chemical Co., Richmond, CA; CDL:249713-B)

00154126 Chen, Y. (1981) Degradation Products of [Ethyl-1-carbon 14]-Naled in Tomato and Orange Processed Parts: File No. 721.14. Unpublished study prepared by Chevron Chemical Co. 22 p.

00160765 Breault, G. (1986) Residue of Naled and DDVP in Crops: Laboratory Project Identification: R-196 . Unpublished study prepared by Chevron Chemical Co. 342 p.

40376601 Breault, G. (1987) Naled Citrus Residue Studies: Laboratory Project ID: R196-6874. Unpublished study prepared by Chevron Chemical Co. 11 p.

40407301 Lee, S. (1987) Dibrom 8E Trials for Supporting Mosquito and Fly Label: Lab. Proj. ID 8725925. Unpublished compilation prepared by Chevron Chemical Co. 12 p.

40506401 Lee, S. (1988) Residue Trials in Support of Dibrom Mosquito and Fly Control Use [on Various Raw Agricultural Commodities]: Project No. R196LABEL. Unpublished study prepared by Chevron Chemical Co. 242 p.

40605201 Lee, S. (1988) Magnitude of Dibrom Residues in Alfalfa: Laboratory Project ID R196MRALFALFA. Unpublished study prepared by Chevron Chemical Co. 100 p.

40633601 Lee, S. (1988) Residue Trial in Support of Dibrom Mosquito and Fly Control Use: Final Report: Project ID: R196LABEL. Unpublished study prepared by Chevron Chemical Co. 256 p.

Residue Chemistry Citations (not used):

00151525 Abell, J. (1985) Nature of Residue (Metabolism)--in Plants: Naled. Unpublished study. 5 p.

00154122 Abell, J. (1985) Nature of Residue (Metabolism) - in Livestock: [Naled]. Unpublished study prepared by Chevron Chemical Co. 8 p.

00154129 Cheng, H. (1982) Metabolic Fate of Naled in Chickens after a Single Oral Dose of (Ethyl-1-carbon-14)-Naled: File No. 721.14. Unpublished study prepared by Chevron Chemical Co. 36 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR NALED.

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.240 Residue Chemistry				
171-2. Chemical Identity[3]				
171-3. Directions for Use		(See Index)[4]		
171-4. Nature of the Residue (Metabolism) - Plants	PAIRA	Yes	00154126	No
171-4. Nature of the Residue (Metabolism) - Livestock	PAIRA & plant metabolites	Partially	00126462 00126463	Yes[5]
171-4. Residue Analytical Methods	TGAI & metabolites	Partially	00160765 40506401	Yes[6]
171-4. Storage Stability	TEP & metabolites	Partially	00160765	Yes[7]
171-4. Magnitude of Residue in Plants				
Root and Tuber Vegetables				
- Sugar Beets	TEP	Yes		No
(processed commodities)	TEP	Yes		No
Leaves of Root and Tuber Vegetables				
- Sugar Beets	TEP	Yes		No

(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)?
Leafy Vegetables (except Brassica)				
- Celery	TEP	Partially	00160765	Yes[8]
- Lettuce	TEP	Partially	N/A	Yes[9]
- Spinach	TEP	Partially	N/A	Yes[10]
- Swiss Chard	TEP	Partially	N/A	Yes[10]
Brassica Leafy Vegetables				
- Broccoli	TEP	Partially	00160765	Yes[11]
- Brussels Sprouts	TEP	No	N/A	Yes[12]
- Cabbage	TEP	Partially	00160765	Yes[13]
- Cauliflower	TEP	Partially	00160765	Yes[14]
- Collards	TEP	Partially	00160865	Yes[15]
- Kale	TEP	Partially	N/A	Yes[16]
Legume Vegetables				
- Beans (succulent & dried)	TEP	Partially	00160765	Yes[17]
(processed commodities)	TEP	No	N/A	Yes[18]

(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)?
- Peas (succulent & dried)	TEP	Yes	00160765	No
- Soybeans	TEP	Partially	N/A	Yes[19]
(processed commodities)	TEP	No	N/A	Yes[20]
<u>Foliage of Legume Vegetables</u>				
- Peas Vines & Hay	TEP	Yes	00160765	Yes[21]
- Soybeans Forage & Hay	TEP	Partially	N/A	Yes[22]
<u>Fruiting Vegetables (Except Cucurbits)</u>				
- Eggplant	TEP	No	N/A	Yes[23]
- Peppers	TEP	Partially	N/A	Yes[24]
- Tomatoes	TEP	Partially	N/A	Yes[25]
(processed commodities)	TEP	No	N/A	Yes[26]
<u>Cucurbit Vegetables</u>				
- Cucumbers	TEP	Partially	N/A	Yes[27]
- Melons	TEP	Partially	N/A	Yes[28]
- Pumpkins	TEP	No	N/A	Yes[29]
- Summer Squash	TEP	Partially	N/A	Yes[30]
- Winter Squash	TEP	Yes	N/A	No

(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)?
Citrus Fruits				
- Grapefruit	TEP	Yes	00160765 40376601	No
- Lemons	TEP	Yes	00160765 40376601	No
- Oranges	TEP	Yes	00160765 40376601	No
(processed commodities)	TEP	No	N/A	Yes[31]
- Tangerines	TEP	Yes	00160765 40376601	No
Stone Fruits				
- Peaches	TEP	Partially	N/A	Yes[32]
Small Fruits & Berries				
- Grapes	TEP	Yes	00160765	No
(processed commodities)	TEP	No	N/A	Yes[33]
- Strawberries	TEP	Partially	00160765	Yes[34]
Tree Nuts				
- Almonds	TEP	Yes	N/A	No
(processed commodities)	TEP	Yes	N/A	No
- Walnuts	TEP	Yes	N/A	No
Cereal Grains				
- Rice	TEP	Yes	N/A	No
(processed commodities)	TEP	No	N/A	Yes[35]

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Forage, Fodder, and Straw of Cereal Grains				
- Rice forage & straw	TEP	Yes	N/A	No
Grass Forage, Fodder, and Hay				
- Grass forage & hay (Pasture & Range)	TEP	Partially	00160765	Yes[36]
Non-grass Animal Feeds				
- Alfalfa forage & hay	TEP	Partially	40605201	Yes[37]
Miscellaneous Commodities				
- Cottonseed	TEP	Partially	00160765	Yes[38]
(processed commodities)	TEP	No	N/A	Yes[39]
- Hops	TEP	Partially	N/A	Yes[40]
(processed commodities)	TEP	No	N/A	Yes[41]
- Mushrooms	TEP	Partially	N/A	Yes[42]
- Safflower Seed	TEP	Yes	N/A	No
(processed commodities)	TEP	Yes	N/A	No
- Tobacco	PAIRA	No	N/A	Yes[43]
171-4. Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially	N/A	Reserved[44]

1. Test substance: PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled;

TABLE A. (Continued).

TEP = Typical end-use product; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

2. These references were submitted in response to the Naled Guidance Document dated 6/83. 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 5/2/89 Update to the Naled Index was used to create this document.

5. The Index dated 5/2/89 lists direct uses of naled on poultry, and no metabolism studies pertaining to these uses are available. Therefore, the following additional data are required. A metabolism study in which laying hens receive direct applications of ethyl-[^{14}C]naled in a manner representative of registered uses. Animals must be treated at a concentration that will result in sufficient residues in the tissues for characterization. Animals must be sacrificed 24 hours after treatment and residues characterized in muscle, fat, liver, and eggs.

6. A revised version of the residue analytical method RM-3G-4 which eliminates the recommendation for a particular brand of acetonitrile should be submitted. The registrant should clearly state that the calculation of residue level is to reflect the total residues of naled and its metabolite DDVP (calculated as equivalents of naled).

7. 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 data in support of previously submitted residue data are required only for those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of naled and its metabolite DDVP in commodities stored under the range of conditions and for the range of intervals specified. Crop samples bearing measurable weathered residues or fortified with naled and DDVP 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 metabolite 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

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TABLE A. (Continued).

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.

8. The data submitted in response to the Guidance Document do not reflect use of a D formulation. Data are required depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or celery harvested 4 days after the last of five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA(72%) and FL(20%), since these states accounted for ca. 90% of the 1986 U.S. celery production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, June, 1987, p. 8).

9. No data were submitted in response to the Guidance Document. Data are required depicting residues of naled and DDVP in or on leaf and head lettuce (with and without wrapper leaves) harvested following at least three applications of a representative D formulation at 2 lb ai/A and the 8 lb/gal EC (leaf lettuce only) at 1.8 lb ai/A using ground and aerial equipment. The tests must be conducted in CA, since this state accounted for ca. 70% of the 1986 U.S. lettuce production (Agricultural Statistics Board, NASS, USDA, Vegetables 1986 Summary, June, 1987, p. 12).

10. No data were submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on spinach harvested at the minimum interval following at least five foliar applications of a D and the 8 lb/gal EC formulation at the maximum registered rate, using ground and aerial equipment. The tests must be conducted in CA(25%), OK(6%) or TX(25%), and NJ(6%) or NY(5%), since these states together accounted for ca. 70% of the 1982 U.S. spinach production (1982 Census of Agriculture, Vol. 1, Part 51, p. 352).

11. The data submitted in response to the Guidance Document do not reflect use of a D formulation. Data are required depicting the combined residues of naled and its metabolite DDVP (expressed as naled) in on or broccoli harvested 1 day after the last of five or more ground and aerial applications reflecting the maximum registered use of the 4% D formulation. Tests must be conducted in CA since this state accounted for ca. 90% of the 1986 U.S. broccoli production (Vegetables, 1986 Summary Ag. Statistics Board, NASS, USDA, June 1987, p. 20).

12. The data requested for broccoli will by translation be used to fulfill data requirements for Brussels sprouts.

TABLE A. (Continued).

13. No data were submitted reflecting aerial applications of a representative EC formulation and ground or aerial applications of a D formulation. Data are required depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or cabbage harvested 1 day after the last of five or more aerial applications reflecting the maximum registered use of a representative EC and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA(8%), FL(16%), NY(15%), NC(5%), TX(16%), and WI(9%) since these states accounted for ca. 70% of the 1982 U.S. cabbage production (1982 Census of Agriculture, Vol. 1 Part 51, p. 338).

14. No data were submitted reflecting aerial applications of a representative EC formulation and ground or aerial applications of a D formulation. Data are required depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or cauliflower harvested 1 day after the last of five or more aerial applications reflecting the maximum registered use of a representative EC formulation and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA since this state accounted for ca. 77% of the 1986 cauliflower production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, 6/87, p. 22).

15. No data were submitted reflecting aerial applications of a representative EC formulation and ground and aerial applications of a D formulation. Data are required depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or collards harvested 4 days after the last of five or more aerial applications reflecting the maximum registered use of a representative EC formulation and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in AL(7%), FL(10%), GA(20%), NJ(6%), NC(6%), or SC(9%), and TX(8%) since these states accounted for ca. 66% of the 1982 U.S. collards production (1982 Census of Agriculture, Vol. 1, Part 51, p. 342).

16. The data requested for collards will by translation be used to fulfill the data requirements for kale.

17. No data were submitted reflecting ground and aerial applications of a D formulation. Data are required depicting combined residues of naled and its metabolite DDVP (expressed as naled) in or on beans (dried) harvested 4 days after three or more ground and aerial applications during the fruiting period of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA(12%), ID(11%), MI(21%), NE(13%), and ND(19%) since these states accounted for ca. 76% of the 1987 U.S. dry beans production (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988).

18. Data are required depicting residues in cannery residue prepared from beans bearing measurable

TABLE A. (Continued).

weathered residues are required. If residues concentrate in this feed item, an appropriate feed additive tolerance must be proposed.

19. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on soybeans harvested following five ground and aerial foliar applications, three made during the fruiting period, of the 8 lb/gal EC formulation at 1.5 lb ai/A. The tests must be conducted in IA(18) or MN(10%), MO(8%), IL(17%), and IN(9%) or OH(8%), since these states accounted for ca. 70% of the 1987 U.S. soybean production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

20. No data were submitted in response to the Guidance Document. The Agency has determined that data on grain dust from soybeans are required in addition to data concerning other processed commodities (C. Trichilo, mamorandum dated 2/3/87). Data are required depicting the potential for concentration of the combined residues of naled and DDVP in hulls, meal, crude oil, refined oil and soapstock, and also grain dust processed from soybeans bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

21. Individual tolerances must be proposed for residues in or on pea hay and vines.

22. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on soybeans harvested following five ground and aerial foliar applications, three made during the fruiting period, of the 8 lb/gal EC formulation at 1.5 lb ai/A. The tests must be conducted in IA(18) or MN(10%), MO(8%), IL(17%), and IN(9%) or OH(8%), since these states accounted for ca. 70% of the 1987 U.S. soybean production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88). Individual tolerances must be proposed for residues in or on soybean forage and hay.

23. No data have been submitted in response to the Guidance Document. The data requested for tomatoes will by translation be used to fulfill the requirements for eggplant.

24. No data have been submitted in response to the Guidance Document. The data requested for tomatoes will by translation be used to fulfill the requirements for peppers.

25. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on tomatoes subjected, in separate tests, to each of the following

TABLE A. (Continued).

treatment schedules: (i) five aerial applications, three made during the fruiting period, of the 8 lb/gal EC formulation at 0.9 lb ai/A; (ii) five ground and aerial applications of the 4% D formulation, three made during the fruiting period, at 2 lb ai/A; (iii) five greenhouse spray applications, three made during the fruiting period, of the 8 lb/gal EC formulation at 0.9 lb ai/100 gal; and (iv) 10 greenhouse fumigation applications, five made during the fruiting period, of the RTU and 8 lb/gal EC formulations at 16 fl. oz and 0.28 lb ai, respectively, per 50,000 cu ft. Field trials must be conducted in CA(77%) and FL(9%), since these states accounted for ca. 90% of the 1986 U.S. tomato production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, June, 1987, pp. 16 and 53).

26. No data have been submitted in response to the Guidance Document. Data are required depicting the concentration of the combined residues of naled and DDVP in puree, catsup, juice, wet pomace, and dry pomace processed from tomatoes bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

27. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on cucumbers harvested following (i) five aerial and ground applications, three made during the fruiting period, of the 4% D formulation at 2 lb ai/A; (ii) five aerial and ground applications, three made during the fruiting period, of the 8 lb/gal EC formulation at 1.35 lb ai/A; (iii) 10 greenhouse fumigation applications, five made during the fruiting period, of the 8 lb/gal EC and rtu formulations at 0.28 lb ai and 16 fl. oz, respectively, per 50,000 cu ft. Field trials must be conducted in CA(10%), MI(22%), NC(13%), OH(9%), and WI(8%), since these states accounted for ca. 60% of the 1986 U.S. cucumber production (Agricultural Statistics Board, NASS, USDA, Vegetables, 1986 Summary, June, 1987, p. 49).

28. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on melons harvested following five aerial and ground applications, three made during the fruiting period, of the 4% D formulation at 2 lb ai/A. The tests must be conducted in CA(52%) and TX(21%), since these states accounted for ca. 70% of the 1982 U.S. cantaloupe production (1982 Census of Agriculture, Vol. 1, Part 51, p. 339).

29. No data have been submitted in response to the Guidance Document. The data requested for melons will by translation, fulfill the requirements for data concerning pumpkins.

30. No data have been submitted in response to the Guidance Document. The data requested for cucumbers will by translation, fulfill the requirements for data concerning summer squash.

TABLE A. (Continued).

31. A processing study depicting residues of naled and its metabolite DDVP in dried pulp, oil, molasses, and juice processed from citrus fruit bearing measurable weathered residues is required. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

32. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on peaches harvested following 10 ground applications of the 8 lb/gal EC formulation at 0.68 lb ai/100 gal, sprayed to runoff, and 10 aerial and ground applications of the 4% D formulation at 3.2 lb ai/A. The tests must be conducted in CA(60%), and GA(4%) or SC(14%), since these states accounted for ca. 80% of the 1987 U.S. peach production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

33. A processing study depicting residues of naled and its metabolite DDVP in wet and dry pomace, raisins, raisin waste, and juice processed from grapes bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

34. No data have been submitted reflecting aerial applications. Data are required depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or strawberries harvested one day after the last of five or more aerial applications reflecting the maximum registered use of a representative EC formulation and five or more ground and aerial applications of the 4% D formulation at 2 lb ai/A. Tests must be conducted in CA since this state accounted for ca. 77% of the 1986 strawberries production (Vegetables, 1986 Summary Ag. Statistics Board, NASS, USDA, 6/1987, p. 27).

35. No data have been submitted in response to the Guidance Document. Data are required depicting the concentration of the combined residues of naled and DDVP in hulls, bran, and polished rice processed from rice grain bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

36. No data were submitted following the last of five aerial and ground applications reflecting the maximum registered use of the 4% D formulation. In addition, no residue data for grass hay have been submitted. Data are required depicting combined residues of naled and its metabolite DDVP (expressed as naled) in on or grass forage harvested one day after the last of five aerial or ground applications reflecting the maximum registered use of the 4% D formulation. Tests must be conducted in AR(3%), GA(3%), KS(4%), KY(5%), MO(11%), NY(5%), OH(3%), OK(4%), OR(4%), PA(4%), SD(2%), TN(4%), TX(13%), VA(3%), and WI(2%) which collectively accounted for ca. 70% of the 1982 tame hay production (1982 Census of Agriculture, Vol.1, Part 51, p. 330).

TABLE A. (Continued).

Data depicting residues of naled and its metabolite DDVP (expressed as naled) in or on grass hay to determine if a separate, or increased tolerance should be established for this commodity.

37. No data have been submitted pertaining to residues in or on hay following aerial application. Data are required depicting residues of naled and its metabolite DDVP (expressed as naled) in or on alfalfa hay harvested 4 days following the last of multiple aerial applications reflecting the maximum registered use of a representative EC formulation. Tests must be conducted in CA(9%), CO(3%), IA(6%), or ID(5%), or KS(4%), MI(4%), or MN(7%), NE(5%), ND(4%), OH(3%), PA(3%), SD(6%), WA(2%), and WI(9%) which collectively accounted for ca. 70% of the 1987 U.S. alfalfa grown for hay (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988). Individual tolerances must be proposed for residues in or on alfalfa forage and hay.

38. No data have been submitted reflecting application of a D formulation. Data are required depicting combined residues of naled and its metabolite DDVP in on or cottonseed harvested 4 days after the last of five ground and aerial applications of the 4% D formulation at 1.4 lb ai/A. Tests must be conducted in CA(20%), LA(7%), MS(12%), and TX(32%) since these states accounted for ca. 71% of the 1987 cotton production (Agricultural Statistics Board, NASS, USDA Crop Database, Jan. 1988).

39. No data have been submitted in response to the Guidance Document. A processing study is required depicting residues of naled and its metabolite DDVP (expressed as naled) in meal, hulls, soapstock, crude oil, and refined oil from the processing of cottonseed bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

40. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on hops harvested following five ground and aerial applications of the 4% D and 8 lb/gal EC formulations at 1 and 0.9 lb ai/A, respectively. The tests must be conducted in WA(74%) or OR(18%), since these states accounted for ca. 90% of the 1987 U.S. production of hops (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

41. No data have been submitted in response to the Guidance Document. Data are required depicting the the concentration of the combined residues of naled and DDVP in dried spent hops processed form hops bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

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TABLE A. (Continued).

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42. No data have been submitted in response to the Guidance Document. Data are required depicting the combined residues of naled and DDVP in or on mushrooms collected following 20 applications of the 8 lb/gal EC and 10% RTU formulations at 6.75 oz ai and 5 fl. oz, respectively, per 50,000 cu ft.

43. A residue profile in tobacco leaves following application of the EC formulation of ethyl-^{14}C-naled at the maximum registered use rate must be submitted. If total residues in or on green freshly-harvested tobacco are $\geq$ 0.1 ppm, then residues must be determined in cured or dried tobacco. If residues $\geq$ 0.1 ppm are detected, then pyrolysis products derived from the active ingredient must be characterized and the level of residue in smoke must be quantified.

44. The nature of the residue in poultry is not understood. On receipt of the requested poultry metabolism data, the need for and nature of tolerances for residues of naled in poultry tissues and eggs will be determined, and additional feeding trials may be required.