C. Furlow

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

MAY 24 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Prometryn Product and Residue Chemistry Reregistration Standard Updates. CBRS No(s). 7170 and 7549; DB BARCODE(s) D156978 and D160100, respectively.

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

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

and

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

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

Please note that the use sites field corn and sweet corn do not appear on the product labels of currently registered products. Therefore, tolerances for prometryn residues in or on field corn forage and fodder, popcorn forage and fodder, sweet corn forage and fodder, fresh corn (K+CWHR), and corn grain (40 CFR 180.222[a]) should be revoked. The use site dill also does not appear on currently registered product labels; however, the tolerance with regional registration for prometryn resides in or on dill (40 CFR 180.222[b]) was recently granted to IR-4 and should remain in effect.

Revised data requirement tables are included.

If you need additional input please advise.

Attachment 1: Prometryn Product Chemistry Reregistration Standard Update.

Attachment 2: Prometryn Residue Chemistry Reregistration Standard Update.

Attachment 3: Confidential Appendices A, B, C, D and E.

cc (With Attachments 1, 2, and 3): P. Deschamp, Prometryn Reregistration Standard file, Prometryn Subject File, C. Furlow/J. Burrell (PIB/FOD), and Acurex.

cc (With Attachments 1 and 2): Circulation (7).
cc (Without Attachments): RF.

ATTACHMENT 1

PROMETRYN
(Chemical Code 080805)

TASK 3

Reregistration Standard Update

Product Chemistry

February 15, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
4915 Prospectus Drive
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PROMETRYN

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

INTRODUCTION

A Product Search Listing conducted on 12/05/90 identifies three registered manufacturing-use products of prometryn, the 95% technical (T), EPA Reg. No. 46386-2, registered by Agan Chemical Manufacturers (Makhteshim-Agan (America) Inc.); the 97% technical (T), EPA Reg. No. 100-542, registered to Ciba-Geigy Corporation; and the 95% T registered by Aceto Chemical Company, Inc. EPA Reg. No. 2749-278.

The Prometryn Guidance Document dated March, 1987 requires additional generic and product-specific product chemistry data for the technical product. Agan Chemical Manufacturers has submitted data (1988; MRID 40661701) in response to the Guidance Document. These data are reviewed below for their adequacy in fulfilling data requirements for the Agan Chemical Manufacturers 95% T (EPA Reg. No. 46386-2). Ciba-Geigy Corp. has submitted data (1987; MRID 40356001, 40356002, and 40573701) in response to the Guidance Document. MRIDs 40356001 and 40356002 were reviewed by the Agency (G. Makhijani, 12/04/87, DEB No. 2907). The data presented in MRID 40573701 are reviewed here for their adequacy in fulfilling data requirements for the Ciba-Geigy 97% T (EPA Reg. No. 100-542).

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278).

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

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

SUMMARY

The following Product Chemistry data remain outstanding:

- o For the Agan Chemical Manufacturers 95% T (EPA Reg. No. 46386-2), data are required pertaining to product composition, a discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical methods.

- o For the Ciba-Geigy 97% T (EPA Reg. No. 100-542), data are required pertaining to nominal concentrations, a revised upper certified limit for the active ingredient, a discussion regarding the potential formation of nitrosamines, a discussion of the analytical methods used for the preliminary analysis, a description and validation data for the nitrosamine enforcement method, and additional data to complete the requirements for Guideline Reference Nos. 63-13 and 63-17.

- o All product chemistry data are required for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278).

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

The Prometryn Guidance Document dated March, 1987 requires additional product specific data concerning product composition. Agan Chemical Manufacturers has submitted a Confidential Statement of Formula (1988; MRID 40661701) for the 95% technical product (EPA Reg. No. 46386-2) which is summarized in Confidential Appendix A. The data reviewed in Confidential Appendix A do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition for the Agan 95% T because the nominal concentration of an unidentified compound present at 0.1% was not claimed on the CSF.

Ciba-Geigy Corp. has submitted information (1987; MRID 40573701) on product identity and a Confidential Statement of Formula for the 97% T (EPA Reg. No. 100-542) which is presented in Confidential Appendix A. These data do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition of the 97% T because nominal concentrations are not specified for the active ingredient nor for any of the impurities. Additional data are required.

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278). All data pertaining to this topic are required for this product.

61-2. Starting Materials and Manufacturing Process

The Prometryn Guidance Document dated March, 1987 requires additional generic and product-specific data concerning the starting materials and manufacturing process. Agan Chemical Manufacturers has submitted pertinent information (1988; MRID 40661701) for the 95% T (EPA Reg. No. 46386-2) which is summarized in Confidential Appendix B. These data do not satisfy requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the production process for the 95% T (EPA Reg. No. 46386-2) because complete copies of technical specifications, MSDS sheets, and pertinent documents describing the starting materials were not provided. No description was given of the equipment used to produce the product and how that equipment might consequently influence the product's final composition. No description was given of procedures involving the equipment used for blending product components and for filling and packaging. A description of the manufacturing process conditions favoring production of nitrosamines is also required. Additional data are required.

Ciba-Geigy Corp. has submitted information (1987: MRID 40356001) pertinent to the starting materials and manufacturing process for the 97% T (EPA Reg. No. 100-542). This information was reviewed by G. Makhijani (DEB No. 2907; 12/4/87), who concluded that the data satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2). No additional data for this topic are required for the Ciba-Geigy 97% T.

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278). All data pertaining to this topic are required for this product.

61-3. Discussion of the Formation of Impurities

The Prometryn Guidance Document dated March, 1987 specifies generic and product-specific data requirements for prometryn regarding detailed discussion of formation of impurities, including nitrosamines. In response to the Guidance Document for the 95% T (EPA Reg. No. 46386-2), Agan Chemical Manufacturers submitted information (1988; MRID 40661701) which is presented in Confidential Appendix C. This information does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities in the Agan 95% T (EPA Reg. No. 46386-2) because a discussion was not presented regarding the presence of an unidentified component or the potential formation pathways for nitrosamines. The potential for post-production contamination was not addressed, whether resulting from previous uses of production equipment or reactions of the active ingredients with other components or the product's packaging. Additional information is required.

In response to the Guidance Document for the 97% T (EPA Reg. No. 100-542), Ciba-Geigy submitted information (1987; MRID 40356001), which was reviewed by G. Makhijani (DEB

§158.167 (Guideline Reference No. 61-3) for the 97% T; however, we note that no information is provided regarding the potential for formation of nitrosamines. Additional data are required.

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278). All data pertaining to this topic are required for this product.

62-1. Preliminary Analysis

The Prometryn Guidance Document dated March, 1987 specifies generic and product specific data requirements regarding preliminary analysis. In response to the Guidance Document for the 95% T (EPA Reg. No. 46386-2), Agan Chemical Manufacturers submitted preliminary analysis data (1988; MRID 40661701) which is summarized and 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 95% T (EPA Reg. No. 46386-2) because the analysis for nitrosamines was not reported. Furthermore, the registrant must attempt identification of the unknown compound present at >0.1% by weight of the technical product.

In response to the Guidance Document for the 97% T (EPA Reg. No. 100-542), Ciba-Geigy submitted preliminary analysis data (1987; MRID 40573701) which is summarized and 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 Ciba-Geigy 97% T (EPA Reg. No. 100-542). Step-by-step descriptions of the analytical methods used for the preliminary analysis, along with validation data for each method, were not provided.

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278). All data pertaining to this topic are required for this product.

62-2. Certified Limits

The Prometryn Guidance Document dated March, 1987 specifies generic and product specific data requirements regarding certification of ingredient limits. In response to the Guidance Document, Agan Chemical Manufacturers submitted data (1988; MRID 40661701) which are reviewed in Confidential Appendix A. These data satisfy the requirements of 40 CFR §158.175, (Guideline Reference No. 62-2) regarding certified limits for the Agan 95% T. However, it should be noted that following completion of the additional preliminary analysis requested, new certified limits may need to be proposed. Certifications and certified limits should be submitted on EPA Form 8570-4 (Rev. 2-85).

In response to the Guidance Document, Ciba-Geigy submitted data (1987; MRID 40573701) which are reviewed in Confidential Appendix A. These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the Ciba-Geigy 97% T (EPA Reg. No. 100-542) in that a comparison between the certified limit for prometryn and the values obtained for prometryn during the preliminary analysis reveals that the concentration of the active ingredient may exceed the maximum certified limit. Additional data are required.

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278). All data pertaining to this topic are required for this product.

62-3. Enforcement Analytical Methods

The Prometryn Guidance Document dated March, 1987 specifies that analytical methods be provided to determine the active ingredient and each toxicologically significant impurity (including nitrosamines) for which a certified limit is required. Analytical methods were submitted by Agan Chemical Manufacturers (1988; MRID 40661701). Method validation data are presented in Confidential Appendix E. Analytical method PRO-ATF/3 was used for quantitative evaluations of prometryn by packed gas chromatography. Method PRO-ATF/3 for prometryn prescribes a Chromasorb W-HP packed GC column and dibutylphthalate as an internal standard. Descriptions of methods for impurities are presented in Confidential Appendix E. Methods were referenced but not listed or utilized for determination of inorganic impurities. Method PRO-ATF/3 for detection of prometryn in the 95% T (EPA Reg. No. 46386-2) and the method for the organic impurities in prometryn do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods. Methods for inorganic impurities were referenced but not described or utilized. Validation data were not submitted for any of the methods. Recovery of pure standards or reference substances were not discussed, nor were qualitative confirmatory methods. A method is required for detecting nitrosamines at 1 ppb. Additional data are required.

Enforcement analytical methods were submitted by Ciba-Geigy (1987; MRID 40573701). Method descriptions and validation data are presented in Confidential Appendix E. These data partially satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the 97% T (EPA Reg. No. 100-542). A description of the method used for the determination of nitrosamines, along with the appropriate validation data, is not provided. Additional data are required.

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278). All data pertaining to this topic are required for this product.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Prometryn Guidance Document dated March, 1987 found the existing data inadequate to satisfy the requirements for physical and chemical characteristics of prometryn technical and purified active ingredient 40 CFR §158.190 (Guideline Reference Nos. 63-2 through 63-21). In response, Agan Chemical Manufacturers submitted data (1988; MRID 40661701) pertaining to the outstanding data requirements for the 95% T (EPA Reg. No. 46386-2). Ciba Geigy submitted data (1987; MRID 40356002) regarding the physical and chemical characteristics of the 97% T (EPA Reg. No. 100-542). The physical and chemical characteristics are summarized in the following table.

These data satisfy the requirement of 40 CFR §158.190 (Guideline Reference Nos. 63-2, 63-5, 63-7, 63-8, 63-10, and 63-12) for the Agan 95% T (EPA Reg. No. 46386-2). The following physical and chemical characteristics are still outstanding for the Agan Chemical Manufacturing 95% T (EPA Reg. No. 46386-2): vapor pressure, octanol/water partition coefficient, stability, explodability, storage stability, and corrosiveness (Guideline reference Nos. 63-9, 63-11, 63-13, 63-16, 63-17, and 63-20). Additional data are required.

The Ciba-Geigy data for the 97% T (EPA Reg. No. 100-542) were reviewed by G. Makhijani (DEB No. 2907; 12/4/87). Additional data are required for stability and storage stability. Data are required for the stability of the technical grade of each active ingredient in conjunction with metal and metal ions, normal and elevated temperatures, and exposure to sunlight. The current storage stability information is insufficient in that the specific requirements for experimental temperature and relative humidity have not been addressed. Additional data are required.

No data were submitted for the Aceto Chemical Co. 95% T (EPA Reg. No. 2749-278). All data pertaining to this topic are required for this product.

Table 1. Physical and chemical properties of the prometryn purified active ingredient (PAI), technical grade of the active ingredient (TGAI), and manufacturing use product (MP).

Guidelines Reference No., 40 CFR §158.90; Name of Property		Description (Product; Substrate; EPA Reg. No.; MRID)
63-2.	Color	**white** (95%T; TGAI; 46386-2; 40661701) **white to tan** (97%T; TGAI; 100-542; 40356002)
63-3.	Physical state	**powder** (95%T; TGAI; 46386-2; 40661701) (97%T; TGAI; 100-542; 40356002)
63-4.	Odor	**very faint cheese-like** (95%T; TGAI; 46386-2; 40661701) **odorless** (97%T; TGAI; 100-542; 40356002)
63-5.	Melting Point	**116-119 °C** (95%T; TGAI; 46386-2; 40661701) **118-120 °C** (97%T; TGAI; 100-542; 40356002)
63-6.	Boiling Point	N/A since the TGAI is a solid at room temperature
63-7.	Density, bulk density, or specific gravity	**1.157 g/cm^3 @ 20 °C** (95%T; TGAI; 46386-2; 40661701) **1.16 g/mL @ 20 °C** (97%T; TGAI; 100-542; 40356002)

(continued)

Table 1. (continued)

Guidelines Reference No., 40 CFR §158.90; Name of Property	Description (Product; Substrate; EPA Reg. No.; MRID)
63-8. Solubility	**48 ppm in water at 20-25 °C** (95%T; TGAI; 46386-2; 40661701) **33 ppm in water @ 20 °C** (97%T; TGAI; 100-542; 40356002) Organic Solvent — g/100ml @ 20 °C acetone — 24 dichloromethane — 30 hexane — 0.55 methanol — 16 octan-1-ol — 10 toluene — 17 (95%T; TGAI; 46386-2; 40661701) (97%T; TGAI; 100-542; 40356002)
63-9. Vapor pressure	**1.0×10^{-6} mm Hg @ 20 °C[a]** (95%T; PAI; 46386-2; 40661701) **1.0×10^{-6} mm Hg @ 25 °C** (97%T; PAI; 100-542; 40356002)
63-10. Dissociation constant	**pK = 4.1 at 21 °C** (95%T; PAI; 46386-2; 40661701) **pK_a = 4.09 at 20 °C** (97%T; PAI; 100-542; 40356002)
63-11. Octanol/water partition coefficient	**K_{ow} = 977, log K_{ow} = 2.99** (95%T; PAI; 46386-2; 40661701) **P_{ow} = 1212 (log P = 3.1) @ 25±1 °C** (97%T; PAI; 100-542; 40356002)

(continued)

Table 1. (continued)

Guidelines Reference No., 40 CFR §158.90; Name of Property	Description (Product; Substrate; EPA Reg. No.; MRID)
63-12. pH	**pH of an aqueous dispersion of technical is 6-7** (95%T; TGAI; 46386-2; 40661701) **pH of saturated solution = 6.7 at 20±2 °C** (97%T; TGAI; 100-542; 40356002)
63-13. Stability	**Stable in neutral and slightly acidic or alkaline media hydrolyzed by alkali and mineral acids at elevated temperatures** (95%T; TGAI; 46386-2; 40661701)
63-14. Oxidizing or reducing action	**none observed** (97%T; TGAI; 100-542; 40356002)
63-15. Flammability	**N/A since the technical is not a combustible liquid**
63-16. Explodability	**NFPA Codes - 0 = No danger** **4 = Explodable** **Safety Classification** **1.1 Drying (T) 1** **Grinding (M) 1** **Dust explosion (ST) 1** **1.2 Maximum allowable temperature of heating medium 120 °C** **Airborne Dust Explosion Data** **Modified Hartmann apparatus: 1** **Minimum ignition energy (J): <10** **Bam ignition temperature (°C): >600** **Particle Size: 1%>63μm** (97%T; TGAI; 100-542; 40356002)

(continued)

Table 1. (continued)

Guidelines Reference No., 40 CFR §158.90; Name of Property	Description (Product; Substrate; EPA Reg. No.; MRID)
63-17. Storage stability	**<1% decomposition:** **when stored at room temperature for 12 months** **when stored at 38 °C for 28 weeks** **when stored at 50 °C for 28 weeks** **when stored at 70 °C for 7 weeks** (97%T; TGAI; 100-542; 40356002)
63-18. Viscosity	**N/A since the technical is a solid**
63-19. Miscibility	**N/A since the technical is a solid**
63-20. Corrosiveness	**Carbon steel coupon at 50 °C** **Corrosion rate = 0.01164 mil/year** **No corrosion or pitting were detected** (97%T; TGAI; 100-542; 40356002)

[a] Value of 1.0×10^{6} reported by registrant and Journal of Chromatography reference is incorrect. It should read 1.0×10^{-6} as shown.

Master Record Identification Numbers:

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

Agency Memoranda:

DEB No.	2907
Subject:	Prometryn - EPA Registration No. 100-542 Ciba-Geigy's Response to the Product Chemistry Chapter
From:	G. Makhijani
To:	R. Taylor, J. Miller, and A. Rispin
Dated:	12/04/87
MRIDs:	40356001. 40356002.

Product Chemistry Citations (used):

40661701 Agan Chemical Manuf. Registration Department (1988) Technical Prometryn: Product Chemistry: Unpublished study prepared by Agan Chemical Manufacturers, Inc. 82 p.

40356001 Brown, R.; Lail, L. (1987) Product Chemistry: Technical Prometryne: Study No. PC-87-021. Unpublished study prepared by Ciba-Geigy Corp. 155 p.

40356002 Brown, R.; Lail, L. (1987) Product Chemistry: Technical Prometryne: Study No. PC-87-021. Unpublished study prepared by Ciba-Geigy Corp. 105 p.

40573701 Brown, R. (1987) Technical Prometryn: Product Chemistry: Study No. PC-87-021. Unpublished study prepared by Ciba-Geigy Corp. 79 p.

Product Chemistry Citations (not used):

[These thirteen MRID citations contain data that are not relevant to currently registered manufacturing-use products.]

40114901 Brolis, L. (1986) Technical Prometryn: Product Chemistry Identity and Composition: Unpublished Study prepared by Oxon Italia Spa. 27 p.

40114902 Brolis, L. (1986) Technical Prometryn: Product Chemistry Analysis and Certification of Product Ingredients: Unpublished Study prepared by Oxon Italia Spa. 22 p.

40114903 Brolis, L. (1986) Technical Prometryn: Product Chemistry Physical and Chemical Characteristics: Unpublished Study prepared by Oxon Italia Spa. 11 p.

40354402 Industria Prodotti Chimici SpA. (1987) Prometryne Technical - Product Chemistry: Physical and Chemical Characteristics. Unpublished study. 34 p.

40354401 Industria Prodotti Chomici SpA. (1987) Prometryne Technical - Product Chemistry Data, Product Identity: I.Pi.Ci. Doc. No. 839/87. Unpublished compilation. 79 p.

40520901 Farmer, A. (1988) Product Chemistry for Prometryne 4L. Unpublished study. 8 p.

40584401 I.Pi.Ci. Industria Prodotti Chimici SpA. (1987) Prometryne Technical-- Product Chemistry Data: Analysis and Certification of Product Ingredients: Doc. No. 861/88 III. Unpublished compilation. 100 p.

40589600 Industria Prodotti Chimici, SpA. (1988) Submission of Data in Response to Prometryne Registration Product Chemistry Data. Transmittal of 2 studies.

40589601 Industria Prodotti Chimici, SpA. (1988) Discussion of Revisions to Vol. I: Prometryne Technical - Product Chemistry Data: Product Identity: IPICI-1988-2. Unpublished study. 6 p.

40700301 Agan chemical Manufacturers Ltd. (1986) Prometrex Technical -- Product Chemistry: Addendum. Unpublished compilation. 30 p.

40729600 Industria Prodotti Chimici, SpA. (1988) Submission of Product Chemistry Data in Response to Prometryne Registration Standard. Transmittal of 1 study.

40729601 Industria Prodotti Chimici SpA. (1988) Prometryne Technical -- Product Chemistry: Storage Stability: Document No. 865. Unpublished study. 29 p.

40860800 EPA generated document received from the RD PM for addition to the Prometryn Registration Standard. (Contains 1 study)

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

Data Requirements	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	40661701	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	40661701	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	40661701	Yes[6]
Physical and Chemical Characteristics				
63-2. Color	TGAI	Yes	40661701	No
63-3. Physical State	TGAI	Yes	40661701	No
63-4. Odor	TGAI	Yes	40661701	No
63-5. Melting Point	TGAI	Yes	40661701	No
63-6. Boiling Point	TGAI	N/A[7]	N/A	No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	40661701	No
63-8. Solubility	TGAI or PAI	Yes	40661701	No
63-9. Vapor Pressure	TGAI or PAI	No	40661701	Yes[8]

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	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)?
63-10. Dissociation Constant	TGAI or PAI	Yes	40661701	No
63-11. Octanol/Water Partition Coefficient	PAI	Partially	40661701	Yes[9]
63-12. pH	TGAI	Yes	40661701	No
63-13. Stability	TGAI	Partially	40661701	Yes[10]
Other Requirements				
64-1. Submittal of Samples	TGAI or PAI			

[1]Data requirements pertain to the Agan Chemical Manufacturers 95% T (EPA Reg. No. 46386-2). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Manufacturing-Use Products."

[2]Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient.

[3]These references were submitted in response to the Prometryn Guidance Document dated March 1987. Underlining indicates documents that have been reviewed for this update.

[4]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, complete copies of technical specifications and MSDSs must be provided. In addition, a description of the equipment used for production, blending, and packaging the product is needed. A current technical data sheet for each starting material is required.

[5]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, a discussion regarding the presence of the unidentified compound or the potential formation pathways for nitrosamines is required along with the potential for post-production contamination, whether resulting from previous uses of production equipment or reactions of the active ingredients with other components or the product's packaging.

TABLE A. (Continued)

[6]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, an identification must be provided for the unknown compound present at >0.1% (w/w). Data must be submitted for nitrosamines.

[7]Not required since the technical is a solid at room temperature.

[8]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, data are required for vapor pressure at 25 °C with the correct exponent.

[9]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, the temperature of the partition coefficient measurement is required.

[10]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, data regarding stability upon exposure to sunlight are required.

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

Data Requirements	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	No		Yes[4]
61-3. Formation of Impurities	TGAI	No		Yes[4]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	No		Yes[4]
Physical and Chemical Characteristics				
63-2. Color	TGAI	No		Yes[4]
63-3. Physical State	TGAI	No		Yes[4]
63-4. Odor	TGAI	No		Yes[4]
63-5. Melting Point	TGAI	No		Yes[4]
63-6. Boiling Point	TGAI	N/A[5]		No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	No		Yes[4]
63-8. Solubility	TGAI or PAI	No		Yes[4]
63-9. Vapor Pressure	TGAI or PAI	No		Yes[4]

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	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)?
63-10. Dissociation Constant	TGAI or PAI	No		Yes[4]
63-11. Octanol/Water Partition Coefficient	PAI	No		Yes[4]
63-12. pH	TGAI	No		Yes[4]
63-13. Stability	TGAI	No		Yes[4]
Other Requirements				
64-1. Submittal of Samples	TGAI or PAI			

[1]Data requirements pertain to the Aceto Chemical Co., Inc. 95% T (EPA Reg. No. 2749-278). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Manufacturing-Use Products."

[2]Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient.

[3]These references were submitted in response to the Prometryn Guidance Document dated March 1987. Underlining indicates documents that have been reviewed for this update.

[4]Aceto Chemical Co. Inc. has not responded for the 95% T (EPA Reg. No. 2749-278). All data for this topic are required for this product.

[5]Not applicable since the technical is a solid at room temperature.

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

Data Requirements	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	40356002	No
61-3. Formation of Impurities	TGAI	Partially	40356001	Yes[4]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	40573701	Yes[5]
Physical and Chemical Characteristics				
63-2. Color	TGAI	Yes	40356002	No
63-3. Physical State	TGAI	Yes	40356002	No
63-4. Odor	TGAI	Yes	40356002	No
63-5. Melting Point	TGAI	Yes	40356002	No
63-6. Boiling Point	TGAI	N/A[6]	40356002	No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	40356002	No
63-8. Solubility	TGAI or PAI	Yes	40356002	No
63-9. Vapor Pressure	TGAI or PAI	Yes	40356002	No

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	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)?
63-10. Dissociation Constant	TGAI or PAI		40356002	
63-11. Octanol/Water Partition Coefficient	PAI	Yes	40356002	No
63-12. pH	TGAI	Yes	40356002	No
63-13. Stability	TGAI	No	40356002	Yes[7]
Other Requirements				
64-1. Submittal of Samples	TGAI or PAI			

[1]Data requirements pertain to the Ciba-Geigy Corporation 97% T (EPA Reg. No. 100-542). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Prometryn Manufacturing-Use Products.

[2]Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient.

[3]These references were submitted in response to the Prometryn Guidance Document dated March 1987. Underlining indicates documents that have been reviewed for this update.

[4]Ciba-Geigy responded for the 97% T (EPA Reg. No. 100-542); however, information regarding the potential formation of nitrosamines is required.

[5]Ciba-Geigy responded for the 97% T (EPA Reg. No. 100-542); however, step-by-step descriptions of the analytical methods used for the preliminary analysis and validation data for each method are needed.

[6]Not applicable since the technical is a solid at room temperature.

TABLE A. (Continued)

[7]Ciba-Geigy has responded for the 97% T (EPA Reg. No. 100-542); however, data are required regarding product decomposition in the presence of metals, at normal and elevated temperatures, and upon exposure to sunlight.

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

Data Requirements	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 Identity and Disclosure of Ingredients	MP	No		Yes[4]
61-2. Beginning Materials and Production Process	MP	No		Yes[4]
61-3. Formation of Impurities	MP	No		Yes[4]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	No		Yes[4]
62-2. Certification of Ingredient Limits	MP	No		Yes[4]
62-3. Analytical Methods to Verify Certified Limits	MP	No		Yes[4]
Physical and Chemical Characteristics				
63-2. Color	MP	No		Yes[4]
63-3. Physical State	MP	No		Yes[4]
63-4. Odor	MP	No		Yes[4]
63-7. Density, Bulk Density, or Specific Gravity	MP	No		Yes[4]

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	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)?
63-12. Ph	MP	No		Yes[4]
63-14. Oxidizing or Reducing Action	MP	No		Yes[4]
63-15. Flammability	MP	No	N/A	No
63-16. Explodability	MP	No		Yes[4]
63-17. Storage Stability	MP	No		Yes[4]
63-18. Viscosity	MP	No	N/A	No
63-19. Miscibility	MP	No	N/A	No
63-20. Corrosion Characteristics	MP	No		Yes[4]
Other Requirements				
64-1. Submittal of Samples	MP	No	N/A	No

[1]Data requirements pertain to the Aceto Chemical Company, Inc. 95% T (EPA Reg. No. 2749-278). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Prometryn Technical Grade of the Active Ingredient.

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the Prometryn Guidance Document dated March 1987. Underlining indicates documents that have been reviewed for this update.

TABLE B. (Continued)

[4]Aceto Chemical Company, Inc. has not responded for the 95% T (EPA Reg. No. 2749-278). Add data pertaining to this topic is required for this product.

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

Data Requirements	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 Identity and Disclosure of Ingredients	MP	Yes	40661701	Yes
61-2. Beginning Materials and Production Process	MP	Partially	40661701	Yes[4]
61-3. Formation of Impurities	MP	Partially	40661701	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	Partially	40661701	Yes[6]
62-2. Certification of Ingredient Limits	MP	Yes	40661701	No
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	40661701	Yes[7]
Physical and Chemical Characteristics				
63-2. Color	MP	Yes	40661701	No
63-3. Physical State	MP	Yes	40661701	No
63-4. Odor	MP	Yes	40661701	No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	40661701	No

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	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)?
63-12. pH	MP	Yes	40661701	No
63-14. Oxidizing or Reducing Action	MP	Yes	40661701	No
63-15. Flammability	MP	No	N/A	No
63-16. Explodability	MP	No		Yes[8]
63-17. Storage Stability	MP	No		Yes[8]
63-18. Viscosity	MP	No	N/A	No
63-19. Miscibility	MP	No	N/A	No
63-20. Corrosion Characteristics	MP	No		Yes[8]
Other Requirements				
64-1. Submittal of Samples	MP			

[1]Data requirements pertain to the Agan Chemical Manufacturers 95% T (EPA Reg. No. 46386-2). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Prometryn Technical Grade of the Active Ingredient".

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the Prometryn Guidance Document dated March 1987. Underlining indicates documents that have been reviewed for this update.

TABLE B. (Continued)

[4]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, complete copies of technical specifications and MSDSs and a description of the equipment used for producing, blending, and packaging the product is required. A current technical data sheet for each starting material is required.

[5]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, a discussion regarding the presence of an unidentified component or the potential formation pathways for nitrosamines is required along with the potential for post-production contamination, whether resulting from previous uses of production equipment or reactions of the active ingredients with other components or the product's packaging.

[6]Agan Chemical Manufacturers has responded for the 95% T (EPA Reg. No. 46386-2); however, an identification must be provided for the unknown compound present at $>0.1\%$ (w/w). Data must be submitted for nitrosamines.

[7]Agan Chemical Manufacturers have responded for the 95% T (EPA Reg. No. 46386-2); however, validation data are required for the submitted methods.

[8]Agan Chemical Manufacturers has not responded for the 95% T (EPA Reg. No. 46386-2).

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

Data Requirements	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 Identity and Disclosure of Ingredients	MP	Partially	40573701	Yes[4]
61-2. Beginning Materials and Production Process	MP	Yes	40356002	No
61-3. Formation of Impurities	MP	Partially	40356001	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	Partially	40573701	Yes[6]
62-2. Certification of Ingredient Limits	MP	Partially	40573701	Yes[7]
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	40573701	Yes[8]
Physical and Chemical Characteristics				
63-2. Color	MP	Yes	40356002	No
63-3. Physical State	MP	Yes	40356002	No
63-4. Odor	MP	Yes	40356002	No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	40356002	No

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	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)?
63-12. pH	MP	Yes	40356002	No
63-14. Oxidizing or Reducing Action	MP	Yes	40356002	No
63-15. Flammability	MP	No	N/A	No
63-16. Explodability	MP	Yes	40356002	No
63-17. Storage Stability	MP	No	40356002	Yes[9]
63-18. Viscosity	MP	No	N/A	No
63-19. Miscibility	MP	No	N/A	No
63-20. Corrosion Characteristics	MP	Yes	40356002	No
Other Requirements				
64-1. Submittal of Samples	MP	No	N/A	No

[1]Data requirements pertain to the Ciba-Geigy Corporation 97% T (EPA Reg. No. 100-542). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Prometryn Technical Grade of the Active Ingredient".

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the Prometryn Guidance Document dated March 1987. Underlining indicates documents that have been reviewed for this update.

TABLE B. (Continued)

[4]Ciba-Geigy has responded for the 97% T (EPA Reg. No. 100-542); however, additional information regarding nominal concentrations and certified limits are required.

[5]Ciba-Geigy has responded for the 97% T (EPA Reg. No. 100-542); however, information is required regarding the potential for formation of nitrosamines.

[6]Ciba-Geigy has responded for the 97% T (EPA Reg. No. 100-542); however, step-by-step descriptions of the analytical methods used for the preliminary analysis along with validation data for each method are needed.

[7]Ciba-Geigy has responded for the 97% T (EPA Reg. No. 100-542); however, additional data are required.

[8]Ciba-Geigy has responded for the 97% T (EPA Reg. No. 100-542); however, a description of the methodology for determining nitrosamines along with the appropriate validation data is required.

[9]Ciba-Geigy has responded for the 97% T (EPA Reg. No. 100-542); however, experimental conditions must be explicitly stated, specifically, temperature and relative humidity.

ATTACHMENT 2

PROMETRYN
(Chemical Code 080805)

TASK 3

Reregistration Standard Update

Residue Chemistry

February 15, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709

PROMETRYN

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 3

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PROMETRYN

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 3

INTRODUCTION

The EPA Site Listing dated 12/5/90 identifies registered food/feed uses for the herbicide prometryn on celery, cotton, and pigeon peas (in Puerto Rico only). The 80% wettable powder (WP), 4 lb/gal emulsifiable concentrate (EC), and the 4 lb/gal flowable concentrate (FlC) formulations may be used for preplant incorporated, preemergence, and postemergence applications. Applications with the EC and FlC formulations may be made using ground and aerial equipment.

The Prometryn Guidance Document, dated 3/20/87, identifies outstanding data requirements for storage stability, plant and animal metabolism, crop field trials, and residue analytical methods for plant tissues. The Guidance Document also reserves a decision regarding the requirement for data on the magnitude of the residue in animal products, pending receipt and evaluation of residue data for feed items and metabolism data for plants and animals.

In response to the Prometryn Guidance Document, data pertaining to plant and animal metabolism (MRIDs 41293301, 41293302, and 41293303) have been submitted and reviewed by the Agency [CBRS (formerly DEB) No. 6048, dated 7/10/90]. Data concerning the nature of the residue in celery (MRID 41711301), residue analytical methods (MRIDs 41397202, 41397203, 41711302), storage stability in celery and cotton (MRID 41397204), and the magnitude of the residue in celery (MRID 41445102) are reviewed in this update for their adequacy in fulfilling outstanding data requirements.

Tolerances for residues of prometryn in or on food and feed commodities are expressed in terms of the parent compound (40 CFR §180.222[a] and [b]). The Guidance Document recommends that the tolerance expression be amended to include prometryn and all triazine-containing analogs and metabolites of toxicological concern.

Note to SRRD: The use sites field corn and sweet corn do not appear on the product labels of currently registered products. Therefore, tolerances for prometryn residues in or on field corn forage and fodder, popcorn forage and fodder, sweet corn forage and fodder, fresh corn (K+CWHR), and corn grain (40 CFR 180.222[a]) should be revoked. The use site dill also does not appear on currently registered product labels; however, the tolerance with regional registration for prometryn resides in or on dill (40 CFR 180.222[b]) was recently granted to IR-4 and should remain in effect.

SUMMARY

The following residue chemistry requirements remain outstanding:

- o Data on plant metabolism (celery and cotton).
- o Following completion of plant metabolism studies, representative samples from plant studies should be analyzed using a residue analytical method suitable for enforcement purposes to ensure that all triazine-containing analogs will be detected by this method.
- o Following the completion of the 24-month storage stability study in progress, data are required concerning the decline of residues in storage.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The Prometryn Guidance Document dated March 20, 1987, concluded that the metabolism of prometryn in plants is not adequately understood. It also noted that additional data are required to characterize residues in the mature parts of cotton and celery following postemergence soil applications of [^{14}C]prometryn at or above the maximum registered rate under conditions similar to those specified in the label directions. Uptake, distribution, and metabolism of [^{14}C]prometryn must be characterized, and terminal residues in or on mature plant parts must be quantified and identified. Also, identification of residues must be confirmed by methods such as GC, HPLC, and/or GC/MS.

In response to these requirements, Ciba-Geigy submitted data (MRID 41293301) pertaining to the metabolism of prometryn in cotton. These data were reviewed by R. Perfetti (CBRS No. 6048, dated 7/10/90), who concluded that metabolism in cotton is not understood, because adequately characterized residues comprised $<43\%$ of the total ^{14}C-residues in cotton plants. Ciba-Geigy also submitted data (1990, MRID 41711301) pertaining to the metabolism of prometryn in field-grown celery which are reviewed here.

The celery metabolism data in the current submission do not fulfill requirements because a majority of the residue was not characterized. The registrant conducted two extraction procedures in characterizing ^{14}C-activity in field-grown celery, and only 23.5% of the total radioactive residue (TRR) was conclusively identified following methanol extraction. The metabolite 2-isopropylamino-4,6-(dihydroxy)-s-triazine (GS-11957) was identified as 13.5% (0.047 ppm) and 2-(1-hydroxymethyl-ethylamino)-4-(amino)-6-(hydroxy)-s-triazine (MCO-III-25) was identified as 10% of the TRR (0.035 ppm) from methanolic extraction of mature celery treated with 3.2 lb ai/A [^{14}C]prometryn. Evidence was presented to support the existence of conjugated residues of concern in the methanol fraction of mature celery.

Following Bligh-Dyer/Ting-Dugger (BD/TD) extraction, only 5.3% of the TRR (0.026 ppm) was conclusively identified. Four components of the organic phase of BD/TD extraction (5.3% of the TRR) were conclusively identified: prometryn, 2-(isopropylamino)-4-(amino)-6-(hydroxy)-s-triazine (GS-17794), 2,4-diamino-6-methylthio-s-triazine (GS-26831), and 2,4-bis(isopropylamino)-6-(hydroxy)-s-triazine (GS-11526). The largest component of the organic fraction, 1 to 1.5% of TRR (0.003 to 0.005 ppm), was identified as GS-26831. No components of the BD/TD aqueous fraction, 84.8% of the TRR, were identified. The non-extractable fraction from BD/TD extraction, approximately 10% of the TRR in mature celery, was not characterized. Information concerning sample storage duration and conditions prior to analysis were not provided. The following additional information is required:

- Data depicting the identity and quantity of residues in mature celery plants in order to elucidate terminal residues. Confirmation of the identification of terminal residues using a suitable method, such as MS or HPLC, is also required. The aqueous soluble residues (BD/TD extraction), containing 84.8% of the TRR, and the unidentified soluble residues from methanolic extraction (64.8% of the TRR) should be characterized further. Enzymatic and other hydrolysis procedures, prior to ion-exchange chromatography, could release identifiable residues from these fractions, and better cleanup, separation and additional chromatographic procedures may be employed. In conducting extraction and characterization analyses, the registrant should be advised that extractable and non-extractable activity, as well as identified and unidentified activity, and any losses of ^{14}C-activity are to be reported in terms of the total radioactive residue for a given sample expressed in ppm prometryn equivalents. Raw data expressed as actual values, rather than ranges, are useful in estimating residue levels. The analysis of the 1x treated mature celery samples may provide more information, since these bore the highest total residues. Following completion of the celery metabolism study, representative samples should be analyzed using a residue analytical method suitable for enforcement purposes to ensure that all triazine-containing analogs will be detected by this method.

- The intervals of sample storage must be reported. If the storage duration was greater than 6 months, storage stability data may be needed.

References (used):

MRID(s): 41293301. 41711301. 41711302.

Discussion of the data:

Celery. Ciba-Geigy Corporation submitted data (1990; MRID 41711301) pertaining to the metabolism of prometryn in field-grown celery (variety Utah 5270) treated with uniformly ring-labeled [^{14}C]prometryn (specific radioactivity 14.2 μCi/mg, radiochemical purity 97.6%). Celery was treated with posttransplant broadcast applications of [^{14}C]prometryn 20 days after transplanting. The rates used were equivalent to 1.6 lb ai/A or 3.2 lb ai/A, representing 1x and 2x the normal use rate, respectively. An untreated check plot served as a control.

Whole celery plants were harvested at approximately 50% maturity, 119 and 158 days, respectively, following the 2x and 1x rate applications and at maturity, 158 and 175 days following treatment at 2x and 1x, respectively. The registrant did not provide any rationale for harvest times for the two prometryn rates; the time to maturity for the 2x-treated plot was less than the 1x treated celery for both 50% mature and mature harvests. The harvest dates for the control celery were not indicated.

Approximately one fourth of the crop was randomly selected for harvest at 50% maturity with the remainder harvested at the mature stage. Celery plants harvested at maturity were cut approximately 1.5 inches above the soil line to limit soil radiolabel contamination.

Plant and soil samples were collected in California and composited into two samples per treatment for shipment to Greensboro, NC. All samples were stored frozen after collection and during shipment, and stored at approximately -20 °C prior to analysis. Sample storage conditions and duration prior to shipping were not indicated. The intervals of sample storage prior to analysis also were not reported. The plant samples for each rate and harvest interval were combined and homogenized with dry ice using a Wiley Mill.

Total Radioactive Residues (TRR)

Samples were analyzed for total radioactivity by combustion and liquid scintillation spectrophotometry (LSS). The limit of detection of the radioassay was 0.016 ppm. The TRR in celery following treatment at 1.6 (1x) and 3.2 (2x) lb ai/A is listed in Table 1. The TRR in or on celery treated with [^{14}C]prometryn at the 1x rate was 0.347 ppm for 50% mature and 0.484 ppm for mature celery. The TRR in or on celery samples resulting from the 2x [^{14}C]prometryn treatment was 0.734 and 0.345 ppm for 50% mature and mature celery, respectively.

Extraction

Two extraction procedures were performed on ^{14}C-residues in celery. The first method employed a sequential residue extraction by the Bligh-Dyer/Ting-Dugger (BD/TD) procedure using a combination of chloroform, methanol, and water as extraction solvents in various ratios. Extracts and solids were analyzed for radioactivity by LSS directly and following

combustion, respectively. The distribution of the TRR in organic, polar and non-extractable fractions following the Bligh-Dyer/Ting-Dugger procedure are presented in Table 1. The recovery of ^{14}C-activity was 100.4% for mature celery treated at 1x and 88.2% for 2x treated samples. The non-extractable fraction (BD/TD) was 10.3 and 10.8% of TRR for mature celery samples. The non-extractable fraction was not characterized further.

Table 1. TRR and its distribution following Bligh-Dyer/Ting-Dugger extraction of celery plants treated with [^{14}C]prometryn in field studies (MRID 41711301).

Maturity of Matrix	Rate (lb ai/A)	TRR (ppm)[b]	percent of TRR[a] Organic	Aqueous	Nonextractable	Total
50%	1.6	0.347	7.0	71.8	10.0	88.8
100%	1.6	0.484	5.3	84.8	10.3	100.4
50%	3.2	0.734	9.7	62.0	13.3	85.0
100%	3.2	0.345	5.9	71.5	10.8	88.2

[a] Results are actual experimental values and were not adjusted to a total sum of 100%.
[b] Parts per million equivalent to [^{14}C]prometryn.

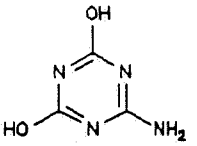
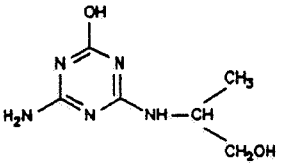
The second method employed a methanolic extraction of residues. Subsamples of plant material from the 2x treatment were extracted with methanol:water (8:2, v/v) by mechanical shaking for 4 hours. The mixture was filtered and re-extracted twice with the same volume of solvent used in the initial extraction. Aliquots were radioassayed to determine ^{14}C-activity prior to characterization by anion exchange, cation exchange, thin-layer, and high-performance liquid chromatography (HPLC). The residue remaining after filtration was air dried, combusted, and radiolabel quantified by LSS to determine non-extractable residues. The methanolic extraction resulted in 88.3% of the TRR (0.342 ppm) in the methanol fraction; 0.9% of the TRR (0.003 ppm) was non-extractable. The recovery of ^{14}C-activity was 89.2% from mature celery treated with [^{14}C]prometryn at 3.2 lb ai/A.

Characterization of Residues

Metabolites were identified by reference to retention times in HPLC and by migration distance in thin-layer chromatography (TLC) of standards. The chemical names and structures of the standards used (prometryn, GS-11526, GS-17791, GS-11354, GS-26831, GS-17794, GS-11957, GS-16141, GS-16158) are presented in the review of plant and animal

metabolism studies submitted previously (CBRS No. 6048, dated 7/10/90). Additional standards used in the current submission are presented in Table 2.

Table 2. Chemical names and molecular structures of standards used in metabolism studies. Additional standards are presented in the Agency review (CBRS No. 6048, dated 7/10/90).

Company Code	Chemical Name	Structure
GS-35713	2-amino-4,6-dihydroxy-s-triazine	
MCO-III-25	2-(1-hydroxymethyl-ethylamino)-4-(amino)-6-(hydroxy)-s-triazine	

Ion-Exchange Chromatography:

Extractable radioactivity from methanol extraction and the aqueous fraction of BD/TD extraction were subjected to anion exchange and cation exchange chromatography.

Anion exchange chromatography was conducted using DEAE Sephadex A-25 resin (Pharmacia Fine Chemical). Samples were loaded in deionized water and eluted with water (500 mL) followed by 0.5M formic acid (500 mL). The flow-rate was approximately 1.5 mL per minute. Fractions of approximately 5 mL were collected, and aliquots were taken for radioanalysis.

Cation exchange chromatography was conducted using Aminex A-4 resin (Bio Rad). The column was equilibrated with 0.1M ammonium formate buffer (pH 4). The sample was added to the column and eluted with 0.1N ammonium formate (250 mL, pH 4):1N ammonium formate (250 mL, pH 6) using a linear gradient. A solution of 3N ammonium hydroxide (100 mL) was used as the final eluant. The flow-rate was approximately 1.5 mL

per minute, and 5 ml fractions were collected. Cation exchange chromatography was also conducted using another column packed with Aminex A-4 resin eluting at a flow-rate of 2 mL per minute with 0.1N ammonium formate (pH 4, 5 min.), followed by a linear gradient of 0.1N ammonium formate (pH 4) to 1.0N ammonium formate (pH 6) for 125 minutes, and 0.1N ammonium hydroxide for 30 minutes. ^{14}C-Activity was quantified using an on-line radioisotope detector.

Anion exchange fractions of methanolic extraction were cleaned up by applying samples to a column packed with XAD-4 resin (Rohm-Haas). Water (1 L) was added to the column followed by elution with methanol (1 L). The resulting methanol fraction was subjected to cation exchange, TLC and HPLC; the aqueous fraction was not characterized.

Size Exclusion Chromatography:

Samples from cation exchange zone 1 of methanolic extraction were subjected to size exclusion chromatography (Sephadex 5-15). Samples were eluted with water (1.5 mL/minute), and 5 mL fractions were collected.

High Performance Liquid Chromatography (HPLC):

Four HPLC systems were utilized for characterization of residues in celery. Non-labeled standards were injected prior to sample analysis. Peaks were identified through ultraviolet absorbance at 240 nm, and ^{14}C-activity was quantified by an on-line radioisotope detector. HPLC fractions were collected using a fraction collector. The following solvent systems were employed:

System 1: ODS-1 analytical column (250 x 4.6 mm i.d., 5 micron, Spherisorb). The solvent system used was: phosphate buffer (20mM, pH 3.2):acetonitrile (95:5) to phosphate buffer:acetonitrile (5:95) in a linear gradient over 20 minutes. The flow-rate was 1 mL per minute.

System 2: ODS-AQ analytical column (23 x 4.0 mm i.d., 5 micron, YMC). The solvent system used was: water:acetonitrile (95:5) to water:acetonitrile (5:95) over 20 minutes in a linear gradient.

System 3: YMC-AQ semi-preparative column (250 x 10 mm i.d., 5 micron). The solvent system used was: water:acetonitrile (95:5) to water:acetonitrile (5:95) over 20 minutes in a linear gradient with a 2 mL per minute flow-rate.

System 4: Cyclobound 1 column (250 x 4.6 mm i.d.). The solvent system used was acetonitrile (100%) for 10 minutes followed by a linear gradient of 100% acetonitrile to 100% water over 15 minutes. The flow-rate was not provided.

Thin-Layer Chromatography (TLC):

Four TLC systems were used with silica gel and aluminum oxide plates. ^{14}C-Activity was monitored by exposure to autoradiography, imaging with a spark chamber, and a radioisotope TLC scanner.

System 1: ethyl acetate
System 2: chloroform:methanol:formic acid:water (75:20:4:2)
System 3: n-butanol:glacial acetic acid:water (134:33:33)
System 4: methylene chloride:acetone (7:3)

Mass spectrometry (MS):

Mass spectrometry was used to confirm identification of metabolites.

Chemical modifications:

Chemical modifications (esterification, acetylation, enzyme hydrolysis) were conducted on samples from methanolic extraction and the aqueous fraction of BD/TD extraction to aid in characterization of metabolite functional groups.

Evaporated samples were esterified by the addition of 3N hydrochloric acid in n-butanol (100 μL). Each sample was sealed and heated at 100 °C for 15 minutes, then cooled, evaporated to dryness and solubilized in methanol (100 μl) prior to analysis by TLC or HPLC.

Evaporated samples were acetylated by the addition of dry pyridine (100 μL) and acetic anhydride (900 μL). Samples were sealed and left overnight at room temperature, evaporated to dryness, and solubilized in methanol (100 μl) prior to analysis by TLC and HPLC.

Enzyme hydrolysis was conducted to determine the presence of conjugated metabolites. Samples were incubated in a shaker bath with cellulase enzyme ($\approx$1 mg) in 1 mL of 0.1N sodium acetate buffer (pH 4.6) for $\geq$12 hours at 37 °C. Hydrolyzed samples were analyzed by TLC or HPLC. Some of the hydrolyzed samples were manipulated further by lyophilization, solubilization in water (1 mL), and partitioning with ethyl acetate (1.5 x the volume), with radioactivity quantified in both fractions. In some cases, the aqueous soluble fraction was cleaned up with a C18 Sep-Pak prior to lyophilization, solubilization in methanol and water, and analysis by TLC and HPLC.

Bligh-Dyer/Ting-Dugger (BD/TD) Extraction:

Radioactivity in fractions resulting from BD/TD extraction is presented in Table 1. The organic fraction of mature celery samples treated with 2x [^{14}C]prometryn was characterized by one- and two-dimensional TLC and reverse phase HPLC. The registrant tentatively

identified: 2,4-diamino-6-hydroxy-s-triazine (GS-17791), 2-amino-4,6-dihydroxy-s-triazine (GS-35713), 2-isopropylamino-4,6-(dihydroxy)-s-triazine (GS-11957), 2-amino-4-isopropylamino-6-methylthio-s-triazine (GS-11354), 2,4-bis(isopropylamino)-6-methylsulfoxide-s-triazine (GS-16141), and 2,4-bis(isopropylamino)-6-methylsulfone-s-triazine (GS-16158) as metabolites present in the organic fraction (BD/TD). Four components [prometryn; 2-isopropylamino-4-amino-6-(hydroxy)-s-triazine (GS-17794); 2,4-diamino-6-methylthio-s-triazine (GS-26831); 2,4-bis(isopropylamino)-6-(hydroxy)-s-triazine (GS-11526)] were identified by both TLC and HPLC analysis. The registrant reported that the metabolite GS-26831, the largest peak of the organic fraction, comprised 15 to 20% of the ^{14}C-activity in this fraction for approximately 1 to 2.5% of the TRR (0.003 to 0.005 ppm). Raw data values were not provided for the peaks identified and for the particular HPLC and TLC system used for the scans.

The aqueous fraction of BD/TD extraction contained the majority of ^{14}C-activity (Table 1) and was characterized by anion chromatographic separation resulting in neutral and basic peaks (A and B) and an acidic peak (C) (Table 3). Peaks A and B, isolated by anion exchange chromatography, were subsequently subjected to cation exchange chromatography (CEC) resulting in nine zones of ^{14}C-activity. Zone 4 of CEC comprised 26.4% (0.128 ppm) of the TRR in mature celery treated at the 1x and 26.7% of the TRR (0.092 ppm) for the 2x samples. The other zones, resulting from CEC on peaks A and B, each contained <0.05 ppm of ^{14}C-residues. A sub-sample of the aqueous soluble fraction was subjected to esterification treatment followed by CEC, resulting in some components of this fraction eluting later (more basic). The registrant suggested that later eluting components following this procedure indicates esterification of carboxylic acid functional groups that are present in amino acids or other components. No further characterization was conducted with the BD/TD extraction aqueous fraction. The non-extractable fraction (BD/TD extraction) of mature celery, comprising 10.3 and 10.8% of the TRR, was not characterized.

Table 3. TRR and its distribution resulting from anion exchange chromatography of the aqueous fraction of Bligh-Dyer/Ting-Dugger extracted mature celery samples treated at 1.6 (1x) and 3.2 lb ai/A (2x).

Fraction	% of TRR[a] 1x	2x
Aqueous Soluble	84.8	71.5
Peak A - Neutral	54.1	62.1
Peak B - Basic	26.3	24.2
Peak C - Acid	8.8	10.5

[a] Results are actual experimental values and were not adjusted to a total sum of 100%.

Methanolic extraction:

Results of ion-exchange chromatography of the methanolic extraction of mature celery are summarized in Table 4. The filtrate resulting from the methanolic extraction of residues of 3.2 lb ai/A [^{14}C]prometryn-treated celery were concentrated by rotary evaporation and were separated by anion exchange chromatography, resulting in neutral and basic components (peaks A and B) and acidic components (peak C). Peaks A and B combined were then purified by passing through an XAD-4 resin column. The XAD column was eluted with methanol and cation exchange chromatography was conducted on the methanol fraction. A majority of the combined peaks A and B (86.2%, 0.273 ppm) was in the methanol fraction after passing through the XAD-4 resin with only 5.8% (0.018 ppm) in the aqueous fraction. The methanolic fraction was reduced in volume and subjected to cation exchange chromatography. Peak C (15.0% of the TRR, 0.051 ppm) from anion exchange chromatography and the aqueous fraction resulting from XAD column cleanup (5.8% of the TRR, 0.018 ppm) were not characterized.

Cation exchange chromatography of the methanolic fraction (from anion exchange peaks A and B through an XAD column) resulted in nine zones (identified as zone 1 through zone 5C) of ^{14}C-activity (Table 4).

Table 4. Distribution of TRR from methanolic extraction of mature celery treated with [^{14}C]prometryn at 3.2 lb ai/A in field studies (MRID 41711301).

Fraction	Total Radioactive Residues[a] %	ppm
Plant Material		0.345
Methanol soluble	88.3	0.342
Non-extractable	0.9	0.003
Anion Exchange Separation (methanol soluble)		
Peaks A & B	86.3	0.291
Peak C	15.0	0.051
XAD cleanup (peaks A & B - anion exchange separation)		
Methanol fraction	86.2	0.273
Aqueous fraction	5.8	0.018
Cation Exchange Separation (methanol - from XAD cleanup)		
Zone 1	10.3	0.036
Zone 2	13.5	0.047
Zone 3A	1.5	0.005
Zone 3B	2.7	0.009
Zone 3C	3.8	0.013
Zone 4	30.2	0.104
Zone 5A	2.7	0.009
Zone 5B	4.6	0.016
Zone 5C	4.7	0.016

[a]Results are actual experimental values and were not adjusted to a total sum of 100%; parts per million equivalent to [^{14}C]prometryn.

Zone 1, 10.3% of the TRR, was subjected to size exclusion chromatography, which resulted in two regions (73:27 ratio). The major region consisted of 1 major component and 3 unresolved components when analyzed by one-dimensional TLC. HPLC analysis indicated that zone 1 consisted of 3 components in a ratio of 57:21:17. Acetylation, cellulase treatment, and preparative TLC and MS did not result in identification of this fraction. The registrant postulated that this fraction was a multicomponent mixture of polar metabolites.

Zone 2, 13.5% of the TRR, co-chromatographed with metabolite GS-11957 by HPLC system 1 and two-dimensional TLC (solvent systems 2 and 3). Purification by HPLC, TLC, and subsequent MS were unable to confirm this identification. The registrant indicated that the presence of co-extractables hindered MS analysis.

HPLC analysis indicated at least 4 metabolites comprised zone 3B, 2.7% of the TRR. Two-dimensional TLC (systems 2 & 3), acetylation, and cellulase treatment suggested the presence of sugar conjugates. Two-dimensional TLC of zone 3C, 3.8% of TRR, suggested that this fraction may be sugar conjugates. HPLC analysis indicated that this zone was a mixture of two major components. Acetylation of zone 3C formed a complex mixture of components while cellulase treatment of zone 3C resulted in components which were more polar by HPLC (system 1) and less polar by TLC (system 2). The registrant suggested that the data indicated the possible presence of a mixture of glucose conjugates in zone 3C.

Zone 4 comprised the largest single fraction of cation exchange chromatography, 30.2% of TRR. HPLC analysis (system 1) and two-dimensional TLC (systems 2 & 3) indicated that this zone is comprised of two components (4A, 10% of the TRR; 4B, 20% of the TRR). Fraction 4A co-chromatographed with 2-(1-hydroxymethyl-ethylamino)-4-(amino)-6-(hydroxy)-s-triazine (MCO-III-25) by 2D-TLC. Preparative TLC followed by MS was inconclusive in this identification. Acetylated samples of zone 4A resulted in a mixture of two products (ratio 36:54) and un-reacted 4A by 1D-TLC analysis. Analysis by HPLC (system 3) indicated that acetylated zone 4A had the same retention time as acetylated MCO-III-25. HPLC results were not provided. Zone 4B was purified by 1D-TLC (system 2) prior to MS analysis; MS results were inconclusive. Acetylation of zone 4B resulted in two products (65:19) that were isolated by HPLC (system 3) and 2D-TLC. MS analysis of the acetylated product was inconclusive. The registrant suggested that 4A and 4B were structural isomers that differed only in the position of the hydroxylated side chain because of similar chromatographic properties.

One-dimensional and two-dimensional TLC and HPLC (system 1) analyses indicated that zone 5A, 2.7% of TRR, was comprised of at least two components. Cellulase treatment resulted in one component which was less polar by TLC and more polar by HPLC. Acetylation resulted in multiple products. One-dimensional and two-dimensional TLC of zone 5B, 4.6% of TRR, indicated this zone was comprised of a mixture of components. Acetylation resulted in the formation of two products. Two-dimensional TLC and HPLC suggested that zone 5C (4.7%) consisted of a single component.

Ciba-Geigy also submitted data (1990; MRID 41711302) from a validation/recovery study in which residues of prometryn and it metabolites GS-11354 and GS-26831 in/on celery samples treated with [^{14}C]prometryn were sought using GLC method AG-559. [^{14}C]Prometryn equivalents, determined by LSS, were 0.484 ppm in/on samples of celery prior to extraction, 0.50-0.52 ppm in the initial extract (>100% recovery), and were 0.0069-0.0094 ppm in the final extract (ca. 2% recovery). Residues of prometryn, GS-11354, and GS-26831 in the final extract quantified by GLC/FPD operating in the sulfur-selective mode were each <0.02 ppm (nondetectable). These data indicate that the initial extraction procedures prescribed by method AG-559 quantitatively recover [^{14}C]prometryn-equivalents present in/on celery. However, it appears that subsequent partitioning and cleanup steps do not adequately recover all triazine-containing compounds.

In summary, the qualitative nature of the residue of prometryn in celery is not adequately understood because only 23.5% of the TRR was conclusively identified (methanolic extraction). Metabolite GS-11957 was identified as 13.5% of the TRR (0.047 ppm) and MCO-III-25 as 10% of the TRR (0.035 ppm) from methanolic extraction of mature celery treated with 3.2 lb ai/A [^{14}C]prometryn. The ^{14}C-activity in prometryn treated celery is comprised of soluble fractions that were analyzed by anion exchange chromatography, CEC, TLC and HPLC. Cation exchange separation (peaks A and B of anion exchange separation from methanol extraction) resulted in early eluting (weakly basic) compounds containing GS-11957 (13.5% of TRR), moderately basic components containing MCO-III-25 (10.0% of TRR), and late eluting highly basic components. Two-dimensional TLC suggests that zones 1 and 3 contain sugar conjugates, while enzyme hydrolysis of other zones suggests the presence of conjugated metabolites. Four components of the organic phase of BD/TD extraction (5.3% of the TRR, 0.026 ppm) were identified by both TLC and HPLC: prometryn, GS-17794, GS-26831, and GS-11526. The largest component of the organic fraction, GS-26831, ranged in value from 0.003 to 0.005 ppm for 1 to 1.5% of the TRR. No components of the aqueous fraction from BD/TD extraction (84.8% of the TRR) were identified. The non-extractable fraction, 10.3 (0.05 ppm) and 10.8% (0.04 ppm) of the TRR, was not characterized.

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The Prometryn Guidance Document dated March 20, 1987, concluded that the metabolism of prometryn in animals is not adequately understood, and it required additional data. In response, Ciba-Geigy submitted data (MRIDs 41293302 and 41293303) that were reviewed by R. Perfetti (CBRS No. 6048, dated 7/10/90), who concluded that the submitted data were adequate to delineate the nature of the residue in animals. The major portion of the terminal residues (those compounds comprising >10% of the TRR) in milk; muscle and liver of poultry and goats, goat kidney, poultry fat and eggs, are variously comprised of N-acetyl cysteine of GS-11354, cysteine of GS-11354, melamine, GS-17794, N-acetyl cysteine of prometryn, and GS-26831; CGA-14129 is an additional terminal residue in milk. No additional data are required for this topic.

References (used):

MRID(s): 41293302. 41293303.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Conclusions:

The Prometryn Guidance Document, dated March 20, 1987, concluded that currently, data are not required for residue analytical methods for animal commodities, because there are no tolerances for residues in such commodities. However, deficiencies exist in the residue analytical procedure for enforcing prometryn tolerances in the various plant commodities of concern. The Prometryn Residue Chemistry Chapter (October 14, 1986) indicated that adequate methods were available for collecting data pertaining to residues of prometryn per se in or on plant commodities utilizing a method identical to Method A (ultraviolet spectrophotometric) and Method B (gas chromatographic (GC)) in the Pesticide Analytical Manual (PAM) Vol. II (Pesticide Reg. Sec. 120.222; Analytical Bulletin No. 10). Neither method has been subjected to an Agency validation trial.

In response, Ciba-Geigy Corp. submitted data (MRID 41397202) pertaining to an alternative analytical GC method (AG-559) for collecting data and enforcing tolerances. Data from a successful independent validation of this method are presented in MRID 41397203. The data indicate that method AG 559 adequately recovers prometryn, 2,4-diamino-6-methylthio-s-triazine (GS-26831) and 2-amino-4-isopropylamino-6-methylthio-s-triazine (GS-11354) from celery, cottonseed, cottonseed meal, and cottonseed oil. Pending completion of a successful Agency method validation trial, method AG 559 would be acceptable for enforcement purposes. However, since the qualitative nature of the residue in plants has not been adequately described, an Agency validation trial will not be requested at this time. Should the required plant metabolism data identify additional residues of concern in plants, additional validated analytical methods may be required.

At the present time, no tolerances exist for prometryn residues in animal commodities. The poultry and ruminant metabolism studies (R. Perfetti, CBRS No. 6048, dated 7/10/90) indicate that finite residues of prometryn and its triazine-containing analogs are not likely to be present in meat, milk, poultry, and eggs at detectable levels. Thus, validated analytical methods for data collection and tolerance enforcement for residues in meat, milk, poultry, and eggs are not needed.

References (used):

MRID(s): 41397202. 41397203.

Discussion of the data:

Ciba-Geigy submitted a description, including validation data, of GLC method AG-559 for determining prometryn and metabolites GS-11354 and GS-26831 in or on celery, cottonseed, and cottonseed fractions (1990; MRID 41397202). In addition, the registrant submitted data from an independent laboratory validation of the method (1990; MRID 41397203).

Residues in or on celery, cottonseed, and cottonseed meal are extracted with methanol:water (9:1, v/v), and the extract is refluxed for 1 hour and filtered. The residues are concentrated and acidified with 1 N hydrochloric acid. The mixture is cleaned up by partitioning with hexane. Sodium phosphate is added and the pH is adjusted to 9.5-10 with 50% sodium hydroxide. The alkaline aqueous solution is loaded onto a Chem Elut column packed with diatomaceous earth and eluted with methylene chloride. The residues are then dried down and redissolved in acetone prior to GLC analysis.

Cottonseed oil is dissolved in hexane and residues are partitioned to acetonitrile. The acetonitrile is evaporated and the sample acidified with 1 N hydrochloric acid. Cleanup, beginning with hexane partitioning, proceeds as described above.

Residues are analyzed using GLC with an Ultrabond 20SE 80/100 mesh column and flame photometric detector on the sulfur-sensitive mode. The limit of detection was 0.02 ppm. Recoveries of prometryn and metabolites from samples fortified with each compound at 0.2-1 ppm are presented in Table 5.

Table 5. Recovery of prometryn, GS-11354, and GS-26831 residues from fortified samples of celery, cottonseed, cottonseed meal, and cottonseed oil using analytical method AG-559[a] (MRID 41397202).

Matrix	Fortification level (ppm)	Prometryn (ppm)	%	GS-11354 (ppm)	%	GS-26831 (ppm)	%
Celery	0.02	0.0183	92	0.020	100	0.020	102
	0.02	0.023	114	0.023	114	0.023	116
	0.05	0.041	83	0.046	92	0.046	91
	0.10	0.064	64	0.077	77	0.079	79
	0.50	0.036	71	0.044	88	0.44	89
Cottonseed	0.05	0.035	71	0.043	87	0.045	90
	0.10	0.076	76	0.090	90	0.085	85
	0.50	0.30	61	0.42	84	0.40	80
Cottonseed meal	0.05	0.045	91	0.040	80	0.048	96
	0.10	0.105	105	0.111	111	0.103	103
	0.50	0.41	83	0.49	98	0.44	89
Cottonseed oil	0.02	0.024	119	0.024	118	0.023	115
	0.02	0.019	95	0.020	99	0.018	92
	0.04	0.028	69	0.027	68	0.025	62
	0.04	0.040	100	0.040	101	0.036	90
	0.05	0.043	85	0.045	91	0.042	83
	0.10	0.079	79	0.087	87	0.078	78
	0.10	0.081	81	0.089	89	0.081	81
	0.20	0.154	77	0.169	85	0.151	75
	0.50	0.38	75	0.425	85	0.385	77
	1.0	0.835	83	0.92	92	0.84	84

[a] The control residue value for prometryn, GS-11354 and GS-26831 was <0.0137 ppm for celery and <0.0125 ppm for the cottonseed samples. [b] Samples were fortified before extraction.

Data from independent laboratory validation of method AG-559 (1990; MRID 41397203) are presented in Table 6. For these analyses, the GLC flow rate and column temperatures were modified slightly to lengthen retention times and broaden peaks to increase sensitivity.

Table 6. Recovery of celery and cottonseed fortified with prometryn, GS-11354, and GS-26831 from the method validation of analytical method AG-559 (MRID 41397203).

Matrix	Fortification Level (ppm)	Recovery (%)		
		Prometryn	GS-11354	GS-28631
Celery	0.02	97	107	92
	0.02	86	101	94
	0.05	81	94	81
	0.05	84	96	83
Cottonseed	0.05	120	112	109
	0.05	125	116	110
	0.25	79	92	72
	0.25	74	85	77

[a]The residue level for the control celery was, <0.02 ppm and <0.05 for cottonseed.

STORAGE STABILITY DATA

Conclusions:

The Prometryn Guidance Document, dated 3/20/87, identifies outstanding data requirements regarding the stability of prometryn in celery, cotton, and corn tissues stored at temperatures approximating normal storage conditions. In response, Ciba-Geigy submitted data (MRID 41397204) concerning the storage of prometryn residues in celery and cottonseed. The data indicate that residues of prometryn, GS-11354, and GS-26831 are stable in celery and cottonseed for 99 days at -20 °C. The data requirement for storage stability of prometryn in celery tissues remains outstanding pending submission of data after study completion.

References (used):

MRID: 41397204.

Discussion of the data:

In response to the Guidance Document, Ciba Geigy Corp. (1990, MRID 41397204) submitted data pertaining to the storage stability of prometryn, GS-11354, and GS-26831 residues in celery and cottonseed. This submission represents a 3-month preliminary report of an ongoing 24-month study. Celery and cottonseed samples were fortified with 1.0 ppm prometryn, GS-11354, and GS-26831 in acetone. The samples were analyzed at the beginning of the study and after 1 and 3 months of storage at -20 °C. The results are summarized in Table 7.

Analytical method AG-559 was used to analyze for prometryn, GS-11354, and GS-26831 in fortified celery and cottonseed samples. The analytical method has been reviewed above. The method employs gas chromatography using flame photometric detection (FPD) in the sulfur sensitive mode. The limit of detection of analytical method AG-559 was 0.02 ppm in celery and cottonseed oil and 0.05 ppm in cottonseed and cottonseed meal. The determination of recovery was conducted concurrently with analyses of stored samples. The values for the 0.1 ppm spiked samples were not reported owing to interference with a large peak associated with an optional centrifuge step that was omitted. The average recoveries of prometryn, GS-11354, and GS-26831 in stored fortified celery, not corrected for procedural recovery, is 86.7, 96.8, and 90.2%, respectively. In cottonseed, the average recoveries (not corrected for procedural recovery) for prometryn, GS-11354, and GS-26831 is 82.7, 91.3, and 82.2%, respectively. The average recovery for freshly fortified celery is 91.2, 101.4 and 98.0% for prometryn, GS-11354, and GS-26831, respectively. The recovery for freshly fortified cottonseed is 89.0% for prometryn, 97.6% for GS-11354, and 92.2% for GS-26831.

Table 7. Recovery of prometryn, GS-11354, and GS-26831 from samples fortified with each compound at 1 ppm and stored at -20 °C for varying lengths of time (MRID 41397204).

Commodity	Interval (days)	Prometryn	GS-11354	GS-26831
		----------Recovery (ppm)[a]----------		
Celery	0	0.88, 0.91	0.94, 0.99	0.93, 0.96
	32	0.85, 0.81	0.98, 0.94	0.84, 0.88
	98	1.22, 1.18	0.97, 1.00	1.02, 0.96
Cottonseed	0	0.91, 0.73	0.93, 0.96	0.90, 0.65
	31	1.08, 0.87	0.95, 0.85	0.86, 0.88
	99	0.90, 1.05	0.90, 1.01	1.02, 1.06

[a]Results were corrected for procedural recoveries of < 100%.

These preliminary data do not provide any evidence for decline of residues in or on celery and cottonseed after 3 months in storage at -20 °C. The data requirement for storage stability of prometryn residues in celery tissues remains outstanding pending data submission following completion of the study.

MAGNITUDE OF THE RESIDUE IN PLANTS

The Prometryn Guidance Document, dated March 20, 1987, identifies outstanding data requirements for the magnitude of the residue in or on celery following a single posttransplant application of the 4 lb/gal EC formulation and processed commodities of field corn (crude oil, refined oil, starch, grits, meal, flour). The Guidance Document also states that the tolerance definition should include the parent compound and all triazine-containing analogs and metabolites of toxicological concern.

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

Leafy Vegetables Group

Celery

Tolerance(s):

A tolerance of 0.5 ppm has been established for residues of prometryn in or on celery (40 CFR §180.222[a]).

Use directions and limitations:

The described registered uses are based on the listed product labels submitted to the Agency in response to the 10/6/89 DCI for reregistration of products containing prometryn (EPA Reg. Nos. 10163-94, 100-620, 1812-274, 34704-692, 38652-2, and 38652-4).

The 4 lb/gal EC, 4 lb/gal FlC, and the 80% WP formulations are variously registered for preemergence and postemergence applications to direct seeded, seedbed, and transplanted celery in CA, FL, HI, MI, OH, and WI. All applications are made using conventional ground equipment in a minimum of 20 gal of water/A. A single postemergence seedbed treatment may be made only in FL. Only one preemergence or one postemergence application to direct seeded celery may be made per season. In general, the lower dosage is used on coarse-textured soils and soils low in organic matter, and the higher dosage is used on fine-textured soils and soils high in organic matter. Application rates for specific uses are detailed in the following table.

Application	Site	Formulation(s)	Rate (lb ai/A)	Location
Postemergence	Transplants	4 FlC, 4 EC	1.6-2	WI
		4 EC	1-2	OH
		4 FlC, 4 EC	1-2	MI
		4 EC	1.6-4	HI
		4 FlC, 80 WP	1.6-3.2	HI
		4 EC	0.8-2	FL
		4 FlC, 80 WP	0.8-1.6	FL
		4 EC	1-2.5	CA
		80 WP	1-2	CA
Postemergence	Direct-seeded	4 EC	0.8-1.25	CA
		4 FlC, 80 WP	0.8-1	CA
Preemergence	Direct-seeded	4 EC	1.2-2	CA
		4 FlC, 80 WP	1.2-1.6	CA
Postemergence	Seedbed	4 EC	0.6-1	FL
		4 FlC, 80 WP	0.6-0.8	FL

Conclusions:

The Prometryn Guidance Document, dated March 20, 1987, requires data depicting residues of concern in or on celery following posttransplant application with the 4 lb/gal EC formulation.

In response to the Guidance Document, Ciba Geigy Corporation (MRID 41445102) submitted data indicating that residues of prometryn in or on celery harvested 37-70 days following posttransplant application with the 4 lb/gal EC formulation at the maximum registered rate do not exceed the established 0.5 ppm tolerance for residues of prometryn per se. Data pertaining to prometryn and its metabolites GS-11354 and GS-26831 were also presented indicating that a 0.5 ppm tolerance for total residues of prometryn and metabolites GS-11354 and GS-26831 would be adequate. The requirement for additional crop field trials with celery are reserved pending submission of required plant metabolism, storage stability, and method validation data.

References (used):

MRID(s): 41445102.

Discussion of the data:

Ciba-Geigy Corp. submitted (1990; MRID 41445102) data from seven tests conducted in FL(2), CA(2), MN(1), and MI(2) pertaining to residues of prometryn and its methylthio metabolites GS-11354 and GS-26831 in or on celery harvested 37-70 days following a single broadcast application of the 4 lb/gal EC formulation at 3.2 lb ai/A (1x). An exaggerated rate of 6.4 lb ai/A (2x) was included in some tests as a comparison. Applications were made ca. 6 weeks after transplanting.

Total prometryn residues in or on celery are presented in Table 9. Residues were <0.06-<0.18 ppm, including <0.02-0.14 ppm of prometryn per se for the 3.2 lb rate and <0.07-<0.23 ppm including 0.03-0.19 ppm of prometryn per se for the 6.4 lb rate. Samples were stored for 16 to 20 months (-20.6 to -17.8 °C) at Ciba-Geigy Corp. prior to shipment to EN-CAS Analytical Laboratories, where they were stored frozen prior to analysis.

Samples were analyzed by analytical method AG-559. The method employs gas chromatography using flame photometric detection (FPD) in the sulfur-sensitive mode. Seven control samples bore non-detectable residues (<0.02 ppm). The average procedural recoveries from fortified celery (0.02-0.50 ppm) was 77.2% for prometryn, 98.8% for GS-11354, and 90.9% for GS-26831 using analytical method AG-559.

Table 9. Prometryn and metabolite residues in or on celery resulting from field applications of the 4 lb/gal EC formulation at 3.2 and 6.4 lb ai/A (MRID 41445102).

Location	Rate (lb ai/A)	PHI (days)	Residues (ppm) Prometryn	GS-11354	GS-26831	Storage Interval (months)
FL	3.2	70	<0.02	<0.02	<0.02	20
FL	3.2	70	<0.02	<0.02	<0.02	20
FL	3.2	54	<0.02	<0.02	<0.02	19
FL	3.2	54	<0.02	<0.02	<0.02	19
FL	6.4	54	0.03	<0.02	<0.02	19
CA	3.2	49	0.14	<0.02	<0.02	19
CA	3.2	49	0.06	<0.02	<0.02	19
CA	6.4	49	0.14	<0.02	<0.02	19
CA	3.2	62	<0.02	<0.02	<0.02	16
CA	3.2	62	0.03	<0.02	<0.02	16
CA	6.4	62	0.03	<0.02	<0.02	16
MN	3.2	64	0.03	<0.02	<0.02	16
MN	3.2	64	0.06	<0.02	<0.02	16
MI	3.2	46	0.08	<0.02	<0.02	16
MI	3.2	46	0.08	<0.02	<0.02	16
MI	6.4	46	0.19	<0.02	<0.02	16
MI	3.2	37	0.06	<0.02	<0.02	16
MI	3.2	37	0.12	<0.02	<0.02	16

Geographic representation is adequate. The test states of CA(62%), FL(22%), and MI(8%), collectively account for about 92% of the U.S. celery production (1987 Census of Agriculture, Vol. 1, Part 51). These data indicate that residues of prometryn in or on celery harvested 37-70 days following posttransplant application with the 4 lb/gal EC formulation at the maximum registered rate do not exceed the established 0.5 ppm tolerance. Data pertaining to prometryn metabolites GS-11354 and GS-26831 were also presented.

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

Tolerance(s):

No tolerances have been established for residues of prometryn in meat, milk, poultry, and eggs.

Conclusions:

The Prometryn Guidance Document, dated 3/20/87, reserves the need for additional data and tolerances for residues of prometryn in meat, milk, poultry, and eggs pending receipt and evaluation of required animal metabolism data.

The use sites field corn and sweet corn no longer appear on registered product labels; thus, cotton is the only commodity which would result in livestock dietary exposure to prometryn residues. The maximum dietary burden of prometryn residues is 0.15 ppm for beef cattle (60% cotton feed items), 0.11 ppm for dairy cattle (45% cotton feed items), 0.04 ppm for poultry (15% cotton feed items), and 0.05 ppm for swine (20% cotton feed items).

The Agency review (R. Perfetti, CBRS No. 6048, dated 7/10/90) of ruminant and poultry metabolism data submitted in response to the Prometryn Guidance Document dated 3/20/87 concludes that the qualitative nature of the residue in animals is adequately understood. A lactating goat was dosed at 50 ppm in the diet (ca. 300-450x the dietary burden of beef and dairy cattle), and laying hens were dosed at 83 ppm in the diet (ca. 2000x the dietary burden of poultry). The major portion of the terminal residues (those compounds comprising $>10\%$ of the TRR) in milk; muscle and liver of poultry and goats, goat kidney, poultry fat and eggs, are variously comprised of N-acetyl cysteine of GS-11354, cysteine of GS-11354, melamine, GS-17794, N-acetyl cysteine of prometryn, and GS-26831; CGA-14129 is an additional terminal residue in milk. The available metabolism data indicate that finite residues of prometryn and its triazine-containing analogs are not likely to be present in meat, milk, poultry, and eggs at detectable levels. Thus, conventional feeding studies and tolerances for prometryn residues in meat, milk, poultry, and eggs are not needed.

References (used):

N/A.

Discussion of the data:

N/A.

MASTER RECORD IDENTIFICATION NUMBERS

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

AGENCY MEMORANDA

CBRS No. 6048
Subject: Response to the Prometryn Reregistration Standard: Plant and Animal Metabolism Studies.
From: R. Perfetti
To: R.Engler
Dated 7/10/90
MRID(s) 41293301. 41293302. 41293303.

Residue Chemistry Citations (used):

41293301 Simoneaux, B. (1989) Uptake and Metabolism of Prometryn by Field Grown Cotton (Nature of Residue-- Plant Metabolism): Laboratory/Study Number ABR-89096; SOP Nos. 7.13, 24.85. Unpublished study prepared by Ciba Geigy Corp. 83 p.

41293302 Maynard, M. (1989) Carbon-14-prometryn Distribution, Elimination, and Metabolism in Goats: Lab Project Number ABR-89082; 104925; Study M14-104-4A. Unpublished study prepared by Ciba-Geigy Laboratories, Agrisearch, Inc., and Ciba-Geigy Corp. 97 p.

41293303 Maynard, M. (1989) Carbon-14-prometryn Distribution, Elimination, and Metabolism in Hens: Lab Project Number ABR-89083; BIOL-88015; M22-104-6a. Unpublished study prepared by Ciba-Geigy Laboratories and Ciba-Geigy Corp. 81 p.

41397202 Vargo, J. (1990) Analytical Method for the Determination of Prometryn and Metabolites GS-11354 and GS-26831 in Celery, Cottonseed, and Cottonseed Fractions: Lab Project Number AG-559. Unpublished study prepared by Ciba-Geigy Corp. 36 p.

41397203 McKinney, F. (1990) Method Validation Ruggedness Trial for Ciba-Geigy Method AG-559: Analytical Method for the Determination of Prometryn and Metabolites GS-11354 and GS-26831 in Celery, Cottonseed, and Cottonseed Fractions: Lab Project Number 89-0120 CGAG. Unpublished study prepared by EN-CAS Analytical Laboratories. 16 p.

41397204 Beidler, W. (1990) Storage Stability of Prometryn and Selected Metabolites in Crops under Freezer Storage Conditions (Three Month Interim Report): Lab Project Number: ABR-89117: 104925. Unpublished study prepared by Ciba-Geigy Corp. 101 p.

41445102 Ross, J. (1990) Prometryn in Celery Following Application of Caparol 4L: Residue Summary: Lab Project I.D. ABR-90005; 104925B. Unpublished study prepared by Ciba-Geigy Corp in cooperation with EN-CAS Analytical Laboratories, Inc. 147 p.

41711301 Simoneaux, B. (1990) Prometryn: Characterization of Metabolites Present in Field Grown Celery: Lab Project Number ABR-90041. Unpublished study prepared by Ciba-Geigy Corp. 118 p.

41711302 Vargo, J. (1990) Validation of Analytical Method AG-559 for the Determination of Prometryn, GS-11354, and GS-26831 in Celery: Lab Project Number ABR-90002. Unpublished study prepared by Ciba-Geigy Corp. 39 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR PROMETRYN RESIDUE CHEMISTRY.[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 §158.240 Residue Chemistry					
171-2.	Chemical Identity[4]				
171-3.	Directions for Use			Product label	
171-4.	Nature of the Residue (Metabolism)				
	- Plants	PAIRA	Partially	41293301 41711301 41711302	Yes[5,6,7]
	- Livestock	PAIRA & Plant Metabolites	Yes	41293302 41293303	No
171-4.	Residue Analytical Methods	TGAI & Metabolites	Partially	41397202 41397203	Yes[8]
171-4.	Storage Stability	PAI & Metabolites	Partially	41397204	Yes[9]
171-4.	Magnitude of the Residue in Plants				
	Leafy Vegetables				
	- Celery	TEP	Partially	41445102	Reserved[10]

(Continued, Footnotes Follow)

TABLE A. (Continued)

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)?
	Legume Vegetables				
	- Pigeon peas	TEP	Yes	N/A	No
	Miscellaneous Commodities				
	- Cottonseed	TEP	Yes	N/A	No
	(processed commodities)	TEP	Yes	N/A	No
171-4.	Magnitude of the Residue in Milk/Meat/Poultry/Eggs	TGAI or Plant Metabolites	Yes	N/A	No[11]

[1]Registrant(s) have responded to all data requirement topics specified in the 3/20/87 Guidance Document. The data gaps included in this update address specific deficiencies, if any, in the submitted data.

[2]Test substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = typical end-use product; EP = end-use product.

[3]These references were submitted in response to the Prometryn Guidance Document dated 3/20/87. Underlining indicates documents that have been reviewed for this update.

[4]The same chemical identity data are required as under 40 CFR 158.150-190, with emphasis on impurities that could constitute residue problems.

(Continued, Footnotes Follow)

TABLE A. (Continued)

[5]Ciba-Geigy submitted data pertaining to the metabolism of prometryn in field-grown celery. These data do not fulfill requirements because a majority of the residue was not characterized. Data are required depicting the identity and quantity of residues in mature celery plants in order to elucidate terminal residues. Confirmation of the identification of terminal residues using a suitable method, such as MS or HPLC, is also required. The aqueous soluble residues (BD/TD extraction), containing 84.8% of the TRR, and the unidentified soluble residues from methanolic extraction (64.8% of the TRR) should be characterized further. Enzymatic and other hydrolysis procedures, prior to ion-exchange chromatography, could release identifiable residues from these fractions, and better cleanup, separation and additional chromatographic procedures may be employed. In conducting extraction and characterization analyses, the registrant should be advised that extractable and non-extractable activity, as well as identified and unidentified activity, and any losses of ^{14}C-activity are to be reported in terms of the total radioactive residue for a given sample expressed in ppm prometryn equivalents. Raw data expressed as actual values, rather than ranges, are useful in estimating residue levels. The analysis of the 1x treated mature celery samples may provide more information, since these bore the highest total residues. Following completion of the celery metabolism study, representative samples should be analyzed using a residue analytical method suitable for enforcement purposes to ensure that all triazine-containing analogs will be detected by this method.

[6]The registrant also needs to submit additional information from the cottonseed metabolism study (CBRS No. 6048, dated 7/10/90). The submitted data do not fulfill outstanding requirements regarding metabolism in cotton. The ^{14}C-residues (0.34 ppm prometryn equivalents) present in cottonseed were not adequately characterized, and attempts to characterize ^{14}C-residues in immature cotton plants were only partially successful: identified residues comprised $<43\%$ of the TRR, and included prometryn, GS-11957, GS-17794, and GS-11526. Residues in cottonseed need to be specifically characterized, perhaps following a repeated study using exaggerated levels of prometryn.

[7]The intervals of sample storage must be reported for the metabolism studies. If the storage duration was greater than 6 months, storage stability data may be needed.

[8]Ciba-Geigy Corp. submitted data pertaining to an alternative analytical GC method (AG-559) for collecting data and enforcing tolerances. Data from an independent validation of this method are presented. The qualitative nature of the residue in plants has not been adequately described. Therefore, the suitability of this method for enforcement purposes cannot be assessed at the present time. If additional residues of concern are identified in plants, representative samples from plant metabolism studies should be analyzed to ensure that residues of concern can be detected.

TABLE A. (Continued)

[9]Ciba-Geigy submitted data (MRID 41397204) concerning the storage of prometryn residues in celery and cottonseed. The data indicate that residues of prometryn, GS-11354, and GS-26831 are stable in celery and cottonseed for 99 days at -20 °C. The data requirement for storage stability of prometryn in celery tissues remains outstanding pending submission of data after study completion.

[10]Ciba Geigy Corporation submitted data indicating that residues of prometryn in or on celery harvested 37-70 days following posttransplant application with the 4 lb/gal EC formulation at the maximum registered rate do not exceed the established 0.5 ppm tolerance. Data pertaining to prometryn metabolites GS-11354 and GS-26831 were also presented. The requirement for additional crop field trials with celery are reserved pending submission of required plant metabolism, storage stability, and method validation data.

[11]The Agency review (R. Perfetti, CBRS No. 6048, dated 7/10/90) of ruminant and poultry metabolism data submitted in response to the Prometryn Guidance Document dated 3/20/87 concludes that the qualitative nature of the residue in animals is adequately understood. Cotton is the only commodity which would result in dietary exposure of livestock to prometryn residues. The maximum dietary burden of prometryn residues is 0.15 ppm for beef cattle (60% cotton feed items), 0.11 for dairy cattle (45% cotton feed items), 0.04 ppm for poultry (15% cotton feed items), and 0.05 ppm for swine (20% cotton feed items). The available ruminant and poultry metabolism data indicate that following administration of [^{14}C]prometryn at 300-450x and 2000x the dietary burden, respectively, finite residues of prometryn and its triazine-containing analogs are not likely to be present in meat, milk, poultry, and eggs at detectable levels. Thus, conventional livestock feeding studies and tolerances for prometryn residues in these animal commodities are not needed.

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ATTACHMENT 3

PROMETRYN

(Chemical Code 080805)

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 4 Page(s)
Appendix B: 1 Page(s)
Appendix C: 2 Page(s)
Appendix D: 3 Page(s)
Appendix E: 4 Page(s)

Confidential Appendices to the Scientific Review of the Reregistration Standard Update Report for the pesticide prometryn by the Chemistry Branch II/Reregistration Section [Confidential FIFRA Trade Secret/CBI].

PROMETRYN PRODUCT AND RESIDUE CHEMISTRY

Page _____ is not included in this copy.

Pages 69 through 80 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

X Description of the product manufacturing process

X Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

X The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

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