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

MAR 28 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Response to the Malathion Reregistration Standard: Product Chemistry Data (MRID's # 4094401-40944108, 40966602, 40966603, and 40335801. CBRS # 7469.)

FROM: [redacted]
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: W. J. Boodee, Section Head
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

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

and

L. Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508C)

Attached are three separate reviews of product chemistry data submitted by Chem-Tox Company, A/S Cheminova, and American Cyanamide Company in response to the malathion Reregistration Standard. These studies were reviewed by Dynamac Corporation under supervision of CBRS, HED.

This information has undergone secondary review in CBRS and has been revised to reflect the Branch policies.

Please see our conclusions in the attachment regarding the adequacy of the information provided by the Registrant.

Revised data tables have also been provided for each of the three registrants products.

Printed on Recycled Paper

If you need additional input please advise.

Attachment 1 : Three Reviews of Malathion Product Chemistry Data.

Attachment 2 : Confidential Appendices A, B and C for the A/S Cheminova Product and Confidential Appendices A and B for the American Cyanamide Company Products.

cc: With Attachments 1 and 2: R. B. Perfetti, J. Burrell (PIB/FOD), Malathion Reregistration Standard File, Malathion Subject File, C. Furlow (PIB/FOD), R. Engler (SACB/HED), L. Rossi (RB/SRRD) and Dynamac.

cc: With Attachment 1: Circulation (7).

cc: Without Attachment: RF.

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Attachment 1

DYNAMAC CORPORATION
Environmental

Final Report

MALATHION (CBRS No. 7469)
Task 4: Registrant's Response to Product Chemistry Data Requirements

March 4, 1991

Contract No. 68-D8-0060

Submitted to:
Environmental Protection Agency
[redacted]

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MALATHION (CHEM-TOX; CBRS NO. 7469)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the Malathion Guidance Document, dated 2/88, Chem-Tox Company has submitted a single volume of product chemistry data (CBRS No. 7469; 1987; MRID 40335801) for the 50% formulation intermediate (FI; EPA Reg. No. 45385-66). These data and our conclusions apply only to the enforcement analytical method used to determine malathion per se in the Chem-Tox 50% FI (EPA Reg. No. 45385-66).

62-3. Enforcement Analytical Methods

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to analytical methods which are suitable for enforcement purposes for each active ingredient and additional impurity determined to be of toxicological concern. In response, Chem-Tox has submitted (1987; MRID 40335801) an American Cyanamid gas-liquid chromatography method for the determination of malathion concentration in formulations. Samples and standards are prepared in chloroform with m-diphenoxybenzene as the internal standard. Samples are injected onto a 122-cm borosilicate glass column (4-mm ID) packed with 5% SP 2401 or OV 210 on Gas Chrom Q or Supelcoport (100/120 mesh). The ratio of the response of the product sample and internal standard is compared to that of a known standard. The gas chromatograph is equipped with a flame ionization detector. No validation data were included in the submission.

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) concerning the enforcement analytical method used to determine malathion concentration in the Chem-Tox 50% FI (EPA Reg. No. 45385-66) because no validation data were submitted. Additional data are required.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE MALATHION (CHEM-TOX) TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-2. Beginning Materials and Production Process	TGAI	R	X[3]		
61-3. Formation of Impurities	TGAI	R	X[3]		
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR	X[3]		
Physical and Chemical Characteristics[4]					
63-2. Color	TGAI	R	X[3]		
63-3. Physical State	TGAI	R	X[3]		
63-4. Odor	TGAI	R	X[3]		
63-5. Melting Point	TGAI	R	X[3,5]		
63-6. Boiling Point	TGAI	R	X[3,6]		
63-7. Density, Bulk Density, or Specific Gravity	TGAI	R	X[3]		
63-8. Solubility	TGAI or PAI	R	X[3]		
63-9. Vapor pressure	TGAI or PAI	R	X[3]		
63-10. Dissociation Constant	TGAI or PAI	R	X[3]		
63-11. Octanol/Water Partition Coefficient	PAI	CR	X[3,7]		
63-12. pH	TGAI	CR	X[3,8]		
63-13. Stability	TGAI	R	X[3]		
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[9]	

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TABLE A. (Continued).

1. Data requirements pertain to the Chem-Tox 50% FI (EPA Reg. No. 45385-66). Additional data requirements are listed in the following Table B, "Generic Data Requirements for Malathion Manufacturing-Use Products", for registered technical products.

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

3. Chem-Tox has not responded to data requirements for the 50% FI; all data requirements remain outstanding.

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

5. Data are required if the TGAI is a solid at room temperature.

6. Data are required if the TGAI is a liquid at room temperature.

7. Data are required if the TGAI is organic and nonpolar.

8. Data are required if the TGAI is dispersible in water.

9. If samples are required, the Agency will request them.

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TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MALATHION (CHEM-TOX) MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes] [No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Composition	MP	R	X[3]	
61-2. Beginning Materials & Production/Formulation Process	MP	R	X[3]	
61-3. Formation of Impurities	MP	R	X[3]	
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	MP	CR	X[3]	
62-2. Certified Limits	MP	R	X[3]	
62-3. Enforcement Analytical Methods	MP	R	X[4]	40335801
Physical and Chemical Characteristics[5]				
63-2. Color	MP	R	X[3]	
63-3. Physical State	MP	R	X[3]	
63-4. Odor	MP	R	X[3]	
63-7. Density, Bulk Density, or Specific Gravity	MP	R	X[3]	
63-12. pH	MP	CR	X[3,6]	
62-14. Oxidizing/Reducing Action	MP	CR	X[3,7]	
62-15. Flammability	MP	CR	X[3,8]	
63-16. Explodability	MP	R	X[3,9]	
63-17. Storage Stability	MP	R	X[3]	
63-18. Viscosity	MP	CR	X[3,10]	
63-19. Miscibility	MP	CR	X[3,11]	

(Continued, footnotes follow)

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TABLE B. (Continued).

Data Requirement	Test Substance	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
63-20. Corrosion Characteristics	MP	R	X[3]		
Other Requirements:					
64-1. Submittal of Samples	MP	CR		X[12]	

1. Data requirements pertain to the Chem-Tox 50% FI (EPA Reg. No. 45385-66). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Malathion Technical Grade of the Active Ingredient", for the TGAI of this manufacturing-use product.

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

5 3. Chem-Tox has not responded for the 50% FI; data requirements remain outstanding.

4. Chem-Tox has responded for the 50% FI; however complete validation data must be submitted for the analytical method used to determine the active ingredient.

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

6. Data are required if the product is dispersible with water.

7. Data are required if the product contains an oxidizing or reducing agent.

8. Data are required if the product contains combustible liquids.

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

10. Data are required if the product is a liquid at room temperature.

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TABLE B. (Continued).

11. Data are required if the product is a liquid which is to be diluted with petroleum solvents.
12. If samples are required, the Agency will request them.

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MALATHION (CHEMINOVA; CBRS NO. 7469)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the Malathion Guidance Document, dated 2/88, A/S Cheminova has submitted two volumes of product chemistry data (CBRS No. 7469; 1989; MRIDs 40966602 and 40966603) for the 95% technical (T; EPA Reg. No. 4787-5). These data and our conclusions are discussed below.

61-1. Product Identity and Disclosure of Ingredients
61-2. Description of Starting Materials and Manufacturing Process
61-3. Discussion of Formation of Impurities

The Malathion Guidance Document, dated 2/88 requires updated information concerning the product identity, starting materials and manufacturing process, and a discussion of the formation of impurities in the Cheminova 95% T (EPA Reg. No. 4787-5). Cheminova has not responded for the 95% T; Guidance Document requirements pertaining to these topics remain outstanding.

62-1. Preliminary Analysis

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to preliminary analysis of the Cheminova 95% T (EPA Reg. No. 4787-5). In response, Cheminova has provided (1989; MRID 40966602) preliminary analysis data for five batch samples of the product. These data are presented in Confidential Appendix B and satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis of the 95% T.

62-2. Certification of Limits

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to certified limits for the Cheminova 95% T (EPA Reg. No. 4787-5). In response, Cheminova has submitted (1989; MRID 40966602) a certification of ingredient limits for the product. Data are presented in Confidential Appendix A and satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the Cheminova 95% T; however, these certifications must be submitted on EPA Form 8570-4 (Rev. 2-85).

62-3. Enforcement Analytical Methods

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to analytical methods which are suitable for enforcement purposes for each active ingredient and additional impurity determined to be of toxicological concern. Cheminova has submitted (1989; MRID 40966602) a gas liquid chromatography method (AM 21.1) for the determination of malathion per se. Standards and samples are combined with the internal standard, dipropyl phthalate in acetone, and injected onto a capillary column coated with OV 101. The gas chromatograph is equipped with a flame ionization detector. Quantitation is by comparison of the ratios of samples to internal standard and standards to internal standard. Accuracy data were submitted for a sample of recrystallized malathion with an added known amount of malathion; however, the fortification level and percent recovery were not included. The precisions for six batch samples, each analyzed on five different days, were 0.47, 0.17, 0.16, 0.19, 0.13, and 0.05%.

The analytical methods submitted by Cheminova (1989; MRID 40966602) for determination of the impurities of technical malathion are discussed in Confidential Appendix C.

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the Cheminova 95% T (EPA Reg. No. 4787-5) because incomplete validation data were submitted for the analytical methods used to determine the levels of the active ingredient and impurities of toxicological significance.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to the physicochemical properties of malathion. In response, physical and chemical characteristics for the 95% T (EPA Reg. No. 4787-5) have been submitted by Cheminova (1989; MRID 40966603). These properties are presented in Table 1. The submitted data satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-2 and 63-20) for the 95% T, except for boiling point, vapor pressure, and stability to sunlight (Guideline Reference Nos. 63-6, 63-9, and 63-13). The registrant has submitted published values for these characteristics; actual studies must be performed on the 95% T (EPA Reg. No. 4787-5).

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Table 1. Physical and chemical properties of the 95% T (EPA Reg. No. 4787-5). Data are located in MRID 40966603.

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method]
63-2.	Color	colorless to pale yellow
63-3.	Physical state	liquid
63-4.	Odor	slightly aromatic
63-5.	Melting point	N/A; TGAI is a liquid
63-6	Boiling point	156-157 C at 0.7 mm Hg [WHO Data Sheets on Pesticides, No. 29, VBC/DS/77.29.]
63-7.	Density, bulk density, or specific gravity	1.23 ± 0.01 g/mL density
63-8.	Solubility	Solubility at 20-23 C Solvent — grams/100 mL water — 145 ppm benzene — miscible xylene — miscible ethanol — miscible acetone — miscible kerosene — 4.3 n-hexane — 6.2
63-9.	Vapor pressure	4 x 10^{-5} mm Hg at 30 C [WHO Data sheets on Pesticides, No. 29, VBC/DS/77.29.]
63-10.	Dissociation constant	based on the chemical structure, malathion does not dissociate
63-11.	Octanol/water partition coefficient	K_{ow} = 2000 at 20-23 C
63-12.	pH	3.7-3.8 at 20 C; 50% solution
63-13.	Stability	stable for 2 years in glass containers in the dark at ambient temperatures (20 C); stable for 2 months at 40 and 55 C. sensitive to sunlight (The Philippine Entomologist, 1984); no significant decomposition after storage up to 14

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Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method]
	days at 54 C in the presence of oxidized iron pieces.
63-14. Oxidizing/ reducing action	structure precludes any significant potential as an oxidizing or reducing agent
63-15. Flammability	flashpoint = 162 C; product does not contain combustible liquids [closed tester, ASTM D 93-73/IP 34]
63-16. Explodability	not explosive
63-17. Storage Stability	stable in coated, unopened drums at 20-23 C; accelerated tests at 55 C for 14 days showed no measurable changes in five samples; one sample stored 1 year in a commercial drum at 21-23 C showed no measurable changes.
63-18. Viscosity	30.0 centipoise at 25 C
63-19. Miscibility	see solubility 63-8
63-20. Corrosion Characteristics	non-corrosive in typical packaging; corrosive to iron if stored for long periods of time

(Continued.)

TABLE A. GENERIC DATA REQUIREMENTS FOR THE MALATHION (CHEMINOVA) TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-2. Beginning Materials and Production Process	TGAI	R	X[3]		
61-3. Formation of Impurities	TGAI	R	X[3]		
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR		X	40966602
Physical and Chemical Characteristics[4]					
63-2. Color	TGAI	R		X	40966603
63-3. Physical State	TGAI	R		X	40966603
63-4. Odor	TGAI	R		X	40966603
63-5. Melting Point	TGAI	R		X[5]	
63-6. Boiling Point	TGAI	R	X[6]		40966603
63-7. Density, Bulk Density, or Specific Gravity	TGAI	R		X	40966603
63-8. Solubility	TGAI or PAI	R		X	40966603
63-9. Vapor pressure	TGAI or PAI	R	X[6]		40966603
63-10. Dissociation Constant	TGAI or PAI	R		X	40966603
63-11. Octanol/Water Partition Coefficient	PAI	CR		X	40966603
63-12. pH	TGAI	CR		X	40966603
63-13. Stability	TGAI	R	X[7]		40966603
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[8]	

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TABLE A. (Continued).

1. Data requirements pertain to the Cheminova 95% T (EPA Reg. No. 4787-5). Additional data requirements are listed in the following Table B, "Generic Data Requirements for Malathion Manufacturing-Use Products", for registered technical products.

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

3. Cheminova has not responded to data requirements for the 95% T; all data requirements remain outstanding.

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

5. Data are not required as the TGAI is a liquid at room temperature.

6. Cheminova has responded for the 95% T; however, published literature citations are not adequate and actual data on the product are required.

7. Cheminova has responded for the 95% T; however, published literature citations are not adequate and actual data on the stability of the product to sunlight are required.

8. If samples are required, the Agency will request them.

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TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MALATHION (CHEMINOVA) MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-1. Product Composition	MP	R	X[3]		
61-2. Beginning Materials & Production/Formulation Process	MP	R	X[3]		
61-3. Formation of Impurities	MP	R	X[3]		
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	CR		X	40966602
62-2. Certified Limits	MP	R		X[4]	40966602
62-3. Enforcement Analytical Methods	MP	R	X[5]		40966602
Physical and Chemical Characteristics[6]					
63-2. Color	MP	R		X	40966603
63-3. Physical State	MP	R		X	40966603
63-4. Odor	MP	R		X	40966603
63-7. Density, Bulk Density, or Specific Gravity	MP	R		X	40966603
63-12. pH	MP	CR		X	40966603
62-14. Oxidizing/Reducing Action	MP	CR		X	40966603
62-15. Flammability	MP	CR		X	40966603
63-16. Explodability	MP	R		X	40966603
63-17. Storage Stability	MP	R		X	40966603
63-18. Viscosity	MP	CR		X	40966603
63-19. Miscibility	MP	CR		X	40966603

(Continued, footnotes follow)

TABLE B. (Continued).

Data Requirement	Test Substance	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
63-20. Corrosion Characteristics	MP	R		X	40966603
Other Requirements:					
64-1. Submittal of Samples	MP	CR		X[7]	

1. Data requirements pertain to the Cheminova 95% T (EPA Reg. No. 4787-5). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Malathion Technical Grade of the Active Ingredient", for the TGAI of this manufacturing-use product.

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

3. Cheminova has not responded for the 95% T; data requirements remain outstanding.

4. Certifications must be submitted on EPA Form 8570-4 (Rev. 2-85).

5. Cheminova has responded for the 95% T; however complete validation data must be submitted for the analytical methods used to determine the active ingredient and the impurities of toxicological significance.

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

7. If samples are required, the Agency will request them.

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MALATHION (AMERICAN CYANAMID; CBRS NO. 7469)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the Malathion Guidance Document, dated 2/88, American Cyanamid Company has submitted seven volumes of product chemistry data (CBRS No. 7469; 1988; MRIDs 40944102-40944108) for the 91% technicals (Ts; EPA Reg. Nos. 241-76 and 241-77). Four of these MRIDs (1988; MRIDs 40944105-40944108) contain duplicate data and will not be used in this document. These data and our conclusions are discussed below.

61-1. Product Identity and Disclosure of Ingredients

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to the product identity of the American Cyanamid 91% Ts (EPA Reg. Nos. 241-76 and 241-77). American Cyanamid has not responded to the data requirements regarding product identity for the 91% Ts. Guidance Document data requirements remain outstanding for these products.

61-2. Description of Starting Materials and Manufacturing Process

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to starting materials and the manufacturing process for the American Cyanamid 91% Ts (EPA Reg. Nos. 241-76 and 241-77). In response, American Cyanamid has submitted (1988; MRID 40944102) a description of the manufacturing process for the 91% T (EPA Reg. No. 241-77) which is presented in Confidential Appendix A. These data satisfy the requirements of 40 CFR §158.160-165 (Guideline Reference No. 61-2) regarding the starting materials and the manufacturing process for the American Cyanamid 91% T (EPA Reg. No. 241-77).

American Cyanamid has not responded to data requirements for the other 91% T (EPA Reg. No. 241-76); Guidance Document data requirements remain outstanding for this product.

61-3. Discussion of Formation of Impurities

The Malathion Guidance Document, dated 2/88 requires an updated discussion of the formation of impurities in the American Cyanamid 91% Ts (EPA Reg. Nos. 241-76 and 241-77). In response, American Cyanamid has submitted (1988; MRID 40944102) a discussion of impurities formed during the manufacture of the 91% T (EPA Reg. No. 241-77) which is presented in Confidential

Appendix B. This information satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the American Cyanamid 91% T (EPA Reg. No. 241-77). Although the impurities of the other 91% T (EPA Reg. No. 241-76) were also listed in the discussion, additional information is required concerning the origin of these impurities in this product.

62-1. Preliminary Analysis
62-2. Certification of Limits
62-3. Enforcement Analytical Methods

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to preliminary analysis, certification of limits, and analytical methods which are suitable for enforcement purposes for each active ingredient and additional impurity determined to be of toxicological concern. American Cyanamid has not responded for the 91% Ts (EPA Reg. Nos. 241-76 and 241-77); Guidance Document data requirements pertaining to these topics remain outstanding for these products.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Malathion Guidance Document, dated 2/88 requires updated information pertaining to the physicochemical properties of malathion. In response, physical and chemical characteristics for the 91% Ts (EPA Reg. Nos. 241-76 and 241-77) have been submitted by American Cyanamid (1988; MRIDs 40944103-40944108). These properties are presented in Table 1. The submitted data satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-2 through 63-20) for the 91% Ts (EPA Reg. Nos. 241-76 and 241-77), except for storage stability data (Guideline Reference No. 63-17) for the 91% T (EPA Reg. No. 241-76), for which a study is still in progress.

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Table 1. Physical and chemical properties of the 91% Ts (EPA Reg. Nos. 241-76 and 241-77).

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method] (Product Reg. No.; MRID)
63-2.	Color	pale yellow to amber (241-77; 40944104) (241-76; 40944103)
63-3.	Physical state	clear, moderately viscous oil (241-77; 40944104) (241-76; 40944103)
63-4.	Odor	typical of sulfur-containing compounds (241-77; 40944104) (241-76; 40944103)
63-5.	Melting point	N/A; TGAI is a liquid (241-77; 40944104) (241-76; 40944103)
63-6	Boiling point	decomposition begins at approx. 190 C at 760 mm Hg; gassing begins at 215 C (241-77; 40944104) (241-76; 40944103)
63-7.	Density, bulk density, or specific gravity	1.23 g/mL density at 20 C (241-77; 40944104) (241-76; 40944103)
63-8.	Solubility	soluble to at least 100 g/100 mL at 20 C in: methanol, acetonitrile, acetone, methylene chloride, and toluene; soluble to 5-6 g/100 mL in n-heptane. (241-77; 40944104) (241-76; 40944103)
63-9.	Vapor pressure	3.43 x 10^{-6} mm Hg at 25 C [gas saturation] (PAI; 241-77; 40944104) (PAI; 241-76; 40944103)
63-10.	Dissociation constant	N/A; does not dissociate (PAI; 241-77; 40944104) (PAI; 241-76; 40944103)

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product Reg. No.; MRID)
63-11. Octanol/water partition coefficient	560, log K_{ow} = 2.748 at 25 C (PAI; 241-77; 40944104) (PAI; 241-76; 40944103)
63-12. pH	N/A; neutral compound with low water solubility (241-77; 40944104) (241-76; 40944103)
63-13. Stability	studies at 55 C indicate ca. a 4% loss after 4 weeks; same loss when in the presence of stainless steel #304 and #316, and aluminum alloy. Exposure to sunlight is not a concern as the product is not exposed to sunlight during manufacture, storage, or shipment. Stability studies with valspar resin are in progress. (241-77; 40944104) (241-76; 40944103)
63-14. Oxidizing/ reducing action	expected to have a weak reducing potential, and no oxidising potential (241-77; 40944104) (241-76; 40944103)
63-15. Flammability	flashpoint >96 C [ASTM Method D3828-81] (241-77; 40944104) (241-76; 40944103)
63-16. Explodability	no response at 2 kg/100 cm or 4 kg/80 cm [impact sensitivity] (241-77; 40944104) (241-76; 40944103)
63-17. Storage Stability	less than a 2% loss after 30 months (241-77; 40944104) in progress; minimal loss after 6 mos. at 24-30 C (241-76; 40944103)
63-18. Viscosity	33 centistokes at 25 C [ASTM method DD 445-79] (241-77; 40944104) (241-76; 40944103)

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product Reg. No.; MRID)
63-19. Miscibility	N/A; not an emulsifiable liquid (241-77; 40944104) (241-76; 40944103)
63-20. Corrosion Characteristics	corrosion rates (mils/yr) after 4 weeks at 55 C: carbon steel = 0.04, stainless steel #304 and #316 = 0.01, aluminum alloy #5083 = 0.09. (241-77; 40944104) corrosion rates (mils/yr) after 4 weeks at 55 C: carbon steel = 0.05, stainless steel #304 and #316 = 0.01, aluminum alloy #5083 = 0.04. (241-76; 40944103)

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TABLE A. GENERIC DATA REQUIREMENTS FOR THE MALATHION (AMERICAN CYANAMID) TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-2. Beginning Materials and Production Process	TGAI	R	X[3]		40944102
61-3. Formation of Impurities	TGAI	R	X[4]		40944102
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR	X[5]		
Physical and Chemical Characteristics[6]					
63-2. Color	TGAI	R		X	40944103 40944104
63-3. Physical State	TGAI	R		X	40944103 40944104
63-4. Odor	TGAI	R		X	40944103 40944104
63-5. Melting Point	TGAI	R		X[7]	
63-6. Boiling Point	TGAI	R		X	40944103 40944104
63-7. Density, Bulk Density, or Specific Gravity	TGAI	R		X	40944103 40944104
63-8. Solubility	TGAI or PAI	R		X	40944103 40944104
63-9. Vapor pressure	TGAI or PAI	R		X	40944103 40944104
63-10. Dissociation Constant	TGAI or PAI	R		X	40944103 40944104
63-11. Octanol/Water Partition Coefficient	PAI	CR		X	40944103 40944104
63-12. pH	TGAI	CR		X[8]	40944103 40944104
63-13. Stability	TGAI	R		X	40944103 40944104
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[9]	

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TABLE A. (Continued).

1. Data requirements pertain to the American Cyanamid 91% Ts (EPA Reg. Nos. 241-76 and 241-77; Technical Malathion and CYTHION, respectively). Additional data requirements are listed in the following Table B, "Generic Data Requirements for Malathion Manufacturing-Use Products", for registered technical products.

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

3. American Cyanamid has not responded for the Technical Malathion 91% T (EPA Reg. No 241-76); data requirements remain outstanding. American Cyanamid has adequately responded for the CYTHION 91% T (EPA Reg. No. 241-77).

4. American Cyanamid has responded to data requirements for the 91% Ts; data submitted for the CYTHION 91% T (EPA Reg. No. 241-77) are adequate, while additional data are required on the origin of the impurities listed for the Technical Malathion 91% T (EPA Reg. No. 241-76).

5. American Cyanamid has not responded for the 91% Ts; all data requirements are outstanding.

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

7. Data are not required as the TGAI is a liquid at room temperature.

8. Data are not required as the TGAI is a neutral compound with low water solubility.

9. If samples are required, the Agency will request them.

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TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MALATHION (AMERICAN CYANAMID) MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-1. Product Composition	MP	R	X[3]		
61-2. Beginning Materials & Production/Formulation Process	MP	R	X[4]		40944102
61-3. Formation of Impurities	MP	R	X[5]		40944102
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	CR	X[3]		
62-2. Certified Limits	MP	R	X[3]		
62-3. Enforcement Analytical Methods	MP	R	X[3]		
Physical and Chemical Characteristics[6]					
63-2. Color	MP	R		X	40944103 40944104
63-3. Physical State	MP	R		X	40944103 40944104
63-4. Odor	MP	R		X	40944103 40944104
63-7. Density, Bulk Density, or Specific Gravity	MP	R		X	40944103 40944104
63-12. pH	MP	CR		X[7]	40944103 40944104
62-14. Oxidizing/Reducing Action	MP	CR		X	40944103 40944104
62-15. Flammability	MP	CR		X	40944103 40944104
63-16. Explodability	MP	R		X	40944103 40944104
63-17. Storage Stability	MP	R	X[8]		40944103 40944104
63-18. Viscosity	MP	CR		X	40944103 40944104
63-19. Miscibility	MP	CR		X[9]	40944103 40944104

(Continued, footnotes follow)

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TABLE B. (Continued).

Data Requirement	Test Substance	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
63-20. Corrosion Characteristics	MP	R		X	40944103 40944104
Other Requirements:					
64-1. Submittal of Samples	MP	CR		X[10]	

1. Data requirements pertain to the American Cyanamid 91% Ts (EPA Reg. Nos. 241-76 and 241-77; Technical Malathion and CYTHION, respectively). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Malathion Technical Grade of the Active Ingredient", for the TGAI of this manufacturing-use product.

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

3. American Cyanamid has not responded for the 91% Ts; data requirements remain outstanding.

4. American Cyanamid has not responded for the Technical Malathion 91% T (EPA Reg. No 241-76); data requirements remain outstanding. American Cyanamid has adequately responded for the CYTHION 91% T (EPA Reg. No. 241-77).

5. American Cyanamid has responded to data requirements for the 91% Ts; data submitted for the CYTHION 91% T (EPA Reg. No. 241-77) are adequate, while additional data are required on the origin of the impurities listed for the Technical Malathion 91% T (EPA Reg. No. 241-76).

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

7. Data are not required as the product is a neutral compound with low water solubility.

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TABLE B. (Continued).

8. American Cyanamid has responded for the 91% Ts; data are adequate for the CYTHION 91% T (EPA Reg. No. 241-77), while the study is still in progress and data remain outstanding for the Technical Malathion 91% T (EPA Reg. No. 241-76).

9. Data are not required as the product is not an emulsifiable liquid.

10. If samples are required, the Agency will request them.

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Attachment 2

MALATHION (CHEMINOVA; CBRS NO. 7469)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A:1 Page(s)
Appendix B:2 Page(s)
Appendix C:2 Page(s)

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

Page ___ is not included in this copy.

Pages 31 through 42 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.

✓ Description of the product manufacturing process.

✓ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

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

_____ The document is not responsive to the request.

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