UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

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

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

and

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

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

These documents provide an in-depth analysis of the status of the Endosulfan Product and Residue Chemistry data bases as of 06/01/90. Revised data requirement tables are included.

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

If you need additional input please advise.

Attachment 1: Endosulfan Product Chemistry Registration Standard Update

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

Attachment 3: Endosulfan Residue Chemistry Registration Standard Update

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

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

DYNAMAC
CORPORATION

Final Report

ENDOSULFAN
Task 4: Product Chemistry Registration Standard Update

June 14, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
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ENDOSULFAN

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

INTRODUCTION

A Product Search Listing dated 1/30/90 identifies six manufacturing-use products (MPs) of endosulfan, four technicals (Ts) and two formulation intermediates (FIs). The Velsicol Chemical Corporation 94% T (EPA Reg. No. 876-201) listed in the Product Search Listing, and the Hooker Chemical Corporation 96% T (EPA Reg. No. 935-26) listed in the April, 1982 Endosulfan Guidance Document, have been cancelled. Data submitted for cancelled products will not be reviewed in this document. The endosulfan manufacturing-use products reviewed in this update are listed in Table 1 below.

Table 1. Endosulfan manufacturing-use products.

Registrant	Product	EPA Reg. No.
Hoechst Celanese Corp.	96% T	8340-13
Makhteshim Chemical Works	95% T	11678-5
	35% FI (EC)	11678-25
	35% FI (WP)	11678-26
FMC Corp.	96% T	279-2306

The Endosulfan Guidance Document dated April, 1982 requires additional product-specific chemistry data for endosulfan manufacturing-use products. In response to these requirements, Hoechst submitted data (1983-1984: MRIDs 00128657, 00142995, and 00144958) in support of the 96% T (EPA Reg. No. 8340-13). Makhteshim submitted data in support of the 95% T (EPA Reg. No. 11678-5) (1983: MRIDs 00128661 and 00128662), the 35% FI/EC (EPA Reg. No. 11678-25) (1983: MRID 00128650), and a Confidential Statement of Formula (CSF) dated 5/24/83 in support of the 35% FI/WP (EPA Reg. No. 11678-26). FMC submitted a CSF dated 2/27/84 in support of the 95% T (EPA Reg. No. 279-2306). These data are reviewed below for their adequacy in fulfilling outstanding data requirements.

In response to a 6/9/87 data call-in notice for information on dioxins, Hoechst and Makhteshim submitted product chemistry data for their technical products. Data submitted by Hoechst (1988; MRIDs 40623101 through 40623103) in response to the DCI Notice have been reviewed by the Agency (S. Funk, DEB Memo No. 6087, dated 2/8/90); and it was recommended that the registrant not be required to analyze the technical endosulfan, manufactured by the procedure described in the submission, for halogenated dibenzo-p-

dioxin/dibenzofuran impurities; no further dioxin data are required for this product. Data submitted by Makhteshim (1988; MRID 40496601) were also reviewed by the Agency (S. Funk, DEB Memo No. 6089; dated 2/26/90) and were found to be inadequate. The Agency's specific conclusions concerning the Makhteshim data are presented under the appropriate guidelines.

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 endosulfan.

	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 Endosulfan Product Chemistry data are required:

- For the Hoechst 96% T (EPA Reg. No. 8340-13) data must be submitted pertaining to product composition, starting materials and the manufacturing process, discussion of formation of impurities, preliminary analysis, enforcement analytical methods, oxidizing/reducing action, explodability, and corrosion characteristics.

- For the Makhteshim 95% T (EPA Reg. No. 11678-5) data must be submitted pertaining to starting materials and the manufacturing process, discussion of formation of impurities, preliminary analysis, enforcement analytical methods, and corrosion characteristics.

- For the FMC 96% T (EPA Reg. No. 279-2306), if the registrant confirms that it no longer produces technical endosulfan, then data submitted by Hoechst and Makhteshim for their endosulfan technical products may be applied to the reregistration of the FMC 96% T. However, if FMC still produces technical endosulfan, data pertaining to the following are required: product composition, starting materials and the manufacturing process, discussion of formation of impurities, preliminary

analysis, enforcement analytical methods, and all physical and chemical characteristics.

- For the Makhteshim 35% FI (EPA Reg. No. 11678-25) data must be submitted pertaining to product composition, starting materials and the manufacturing process, discussion of formation of impurities, certified limits, and enforcement analytical methods.

- For the Makhteshim 35% FI (EPA Reg. No. 11678-26) data must be submitted pertaining to product composition, starting materials and the manufacturing process, discussion of formation of impurities, certified limits, enforcement analytical methods, and all physical and chemical characteristics.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Composition

The Endosulfan Guidance Document dated April, 1982 requires additional product-specific data concerning product composition. In response, the registrants have submitted data and CSFs, discussed in Confidential Appendix A.

Data submitted by Hoechst (1983; MRID 00128657) for the 96% T (EPA Reg. No. 8340-13) do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because nominal concentrations were not provided for the active ingredient and impurities. Additional data are required.

Data submitted by Makhteshim (1983; MRID 00128662) for the 95% T (EPA Reg. No. 11678-5) do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because impurities were not identified as such and nominal concentrations could not be determined since the CSF provided presented only "percent by weight" for the listed components. The registrant must submit an updated CSF on EPA form 8570-4 (Rev. 2-85), on which impurities are correctly identified, and appropriate nominal concentrations and certified limits are provided.

In addition, data submitted by Makhteshim (1988; MRID 40496601) for the 95% T (EPA Reg. No. 11678-5) in response to the dioxin DCI Notice were reviewed by the Agency (S. Funk, DEB Memo No. 6089, dated 2/26/90) and were found to be inadequate to satisfy the requirements of the DCI Notice regarding product composition.

The CSF submitted by FMC for the 96% T (EPA Reg. No. 279-2306) does not satisfy the requirements of 40 CFR §158.155 (Guideline

Reference No. 61-1) regarding product composition because impurities were not identified as such, and nominal concentrations were not provided for the active ingredient and impurities of concern (refer to Confidential Appendix A). In addition, there is a discrepancy between this CSF and more recent company correspondence regarding the source of the active ingredient. The registrant must submit an updated CSF, on which impurities are correctly identified, nominal concentrations are provided for the appropriate ingredients, and the source of the active ingredient is correctly identified.

Data submitted by Makhteshim (1983; MRID 00128650) for the 35% FI (EPA Reg. No. 11678-25) do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because the nominal concentration of the active ingredient (based upon the nominal concentration in the source product) was not reported. Additional data are required.

The CSF submitted by Makhteshim for the 35% FI (EPA Reg. No. 11678-26) does not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because the nominal concentration of the active ingredient (based upon the nominal concentration in the source product) was not reported. Additional data are required.

61-2. Starting Materials and Manufacturing Process

The Endosulfan Guidance Document dated April, 1982 identifies product-specific data requirements for endosulfan regarding starting materials and manufacturing/formulation processes. The data and information submitted by the registrants in response to the Guidance Document are summarized in Confidential Appendix B.

Data submitted by Hoechst (1983, 1984; MRIDs 00128657 and 00144958) for the 96% T (EPA Reg. No. 8340-13) and presented in Confidential Appendix B, do not satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the production process because the registrant did not include the following: (i) a statement as to whether the process is batch or continuous; (ii) the duration of each step and of the entire process; (iii) the relative amounts of the materials used; (iv) a description of the manufacturing equipment; (v) a complete description of the reaction conditions controlled (e.g. pH, pressure) during each step of the process; or (vi) a description of the sampling regimen and quality control procedures necessary to assure product consistency. Additional data are required.

Data submitted by Makhteshim (1983; MRID 00128662) for the 95% T (EPA Reg. No. 11678-5) and presented in Confidential Appendix B, do not satisfy the requirements of 40 CFR §158.160-162 (Guideline

Reference No. 61-2) regarding starting materials and the production process because the registrant did not submit the following: (i) a statement as to whether the process is batch or continuous; (ii) the duration of each step and of the entire process; (iii) a complete description of the reaction conditions controlled (e.g. pH, pressure) during each step of the process; (iv) a complete description of purification procedures including solvent recycling; and (v) a description of the sampling regimen and quality control procedures necessary to assure product consistency. Additional data are required. In addition, data submitted by Makhteshim (1988; MRID 40496601) for the 95% T (EPA Reg. No. 11678-5) in response to the dioxin DCI Notice were reviewed by the Agency (S. Funk, DEB No. 6089, 2/26/90) and found to be inadequate in satisfying the requirements of the DCI Notice regarding starting materials and manufacturing process.

Data (starting material sources and specifications) submitted by Makhteshim (1983; MRID 00128650) for the 35% FI (EPA Reg. No. 11678-25) do not satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the formulation process because the registrant did not submit a description of the manufacturing process; including mixing conditions (pH, temperature), addition order of ingredients, duration of the process, and quality control procedures. Additional data are required.

No data were submitted for the Makhteshim 35% FI (EPA Reg. No. 11678-26) pertaining to starting materials and the formulation process. Complete data concerning the starting materials and the formulation process of the 35% FI (EPA Reg. No. 11678-26) are required.

No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

61-3. Discussion of the Formation of Impurities

The Endosulfan Guidance Document dated April, 1982 identifies product-specific data requirements regarding discussion of formation of impurities. In response, the registrants have submitted data, discussed in Confidential Appendix C.

Data submitted by Hoechst (1984; MRID 00144958) for the 96% T (EPA Reg. No.8340-13) do not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities because the registrant did not submit

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discussions pertaining to the following: (i) the possible degradation of the ingredients in the product after its production but prior to use; (ii) post production reactions between ingredients in the product; (iii) the possible migration of components of packaging materials into the pesticide; (iv) the possible carryover of contaminants from production equipment used to produce other products; and (v) process control, purification procedures and quality control measures used to produce the product. Additional information is required.

The information submitted by Makhteshim (1983; MRID 00128662) for the 95% T (EPA Reg. No. 11678-5) does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding the discussion of formation of impurities because the registrant did not discuss the following: (i) the formation of all the impurities listed on the CSF at ≥0.1%; (ii) the possible migration of components of packaging materials into the pesticide; (iii) the possible carryover of contaminants from use of production equipment used to produce other products or substances; (iv) the impurities in the starting materials; and (v) the process control, purification procedures and quality control measures used to produce the product. Additional information is required.

Data submitted by Makhteshim (1988; MRID 40496601) for the 95% T (EPA Reg. No. 11678-5) in response to the DCI Notice have been reviewed by the Agency (S. Funk, DEB Memo No. 6089, dated 2/26/90) and were found to be inadequate to satisfy the requirements of the DCI Notice regarding discussion of formation of impurities. The registrant must submit a discussion of the possible mechanism for the formation of halogenated dibenzodioxins/dibenzofurans. No decision can be made concerning the need for analytical data for halogenated dibenzo-p-dioxin/dibenzofuran compounds in technical endosulfan until this data requirement is fulfilled. Additional data are required.

In response to the Guidance Document requirement for discussion of formation of impurities in the 35% FI (EPA Reg. No. 11678-25), Makhteshim (1983; MRID 00128650) referred to the discussion of formation of impurities in the 95% T (EPA Reg. No. 11678-5; 1983; MRID 00128662). Although, it is expected that no impurities other than those of the technical will be present, the registrant must submit such a statement and a discussion of possible impurities from (i) the degradation of the ingredients in the product after its production but prior to use; (ii) post production reactions between ingredients in the product; (iii) the migration of components of packaging materials into the pesticide; (iv) the carryover of contaminants from use of production equipment used to produce other products or substances; and (v) the process control, purification procedures and quality control measures used to produce the product. Additional information is required.

No data were submitted pertaining to discussion of formation of impurities for the Makhteshim 35% FI (EPA Reg. No. 11678-26). Additional data are required.

No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Endosulfan Guidance Document dated April, 1982 identifies product-specific data requirements regarding preliminary analysis.

Makhteshim submitted data concerning preliminary analysis (1983; MRID 00128662) for the 95% T (EPA Reg. No 11678-5). Samples were taken from six different batches and analyzed for the active ingredient and impurities. The mean of the active ingredient concentration was 95.9 ± 0.5%. These data do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 62-1) regarding preliminary analysis because the registrant did not submit raw data for the active ingredient and the impurities, the mean and standard deviation for all ingredients, and the analytical methods used (including validation data). Additional data are required.

No data pertaining to preliminary analysis were submitted for the Hoechst 96% T (EPA Reg. No. 8340-13). Data requirements for this product are still outstanding.

No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

62-2. Certified Limits

The Endosulfan Guidance Document issued April, 1982 identifies product-specific data requirements for endosulfan regarding certification of ingredient limits. In response, the registrants

have submitted data and CSFs; these data are discussed in Confidential Appendix A.

Data submitted by Hoechst (1983; 00128657) for the 96% T (EPA Reg. No. 8340-13) satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits. No additional data are required; however, the registrant should submit an updated CSF on EPA form 8570-4 (Rev. 2-85).

Data (1983; MRID 00128662) and a CSF submitted by Makhteshim for the 96% T (EPA Reg. No. 11678-5) do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) certified limits were not reported; the registrant should submit an updated CSF, bearing the appropriate certified limits, on EPA form 8570-4 (Rev. 2-85).

A CSF submitted by FMC for the 96% T (EPA Reg. No. 279-2306) satisfies the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the FMC 96% T (EPA Reg. No. 279-2306). However, this CSF disagrees with more recent correspondence from the company regarding the source of the active ingredient, and an updated CSF needs to be submitted. Updated information should be submitted on EPA form 8570-4 (Rev. 2-85).

Data and a CSF submitted by Makhteshim (1983; MRID 00128650) for the 35% FI (EPA Reg. No. 11678-25) do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits because the upper and lower certified limits for the inert ingredients were not included. Additional data are required. Updated information should be submitted on EPA form 8570-4 (Rev. 2-85).

A CSF submitted by Makhteshim for the 35% FI (EPA Reg. No. 11678-26) does not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits because the upper and lower certified limits for the active ingredient and inerts were not included. Additional data are required. Updated information should be submitted on EPA form 8570-4 (Rev. 2-85).

62-3. Enforcement Analytical Methods

The Endosulfan Guidance Document dated April, 1982 specifies product-specific data requirements regarding enforcement analytical methods.

In response to the Guidance Document, Hoechst submitted methods (1983; MRID 00128657) for the determination of endosulfan *per se* and its impurities. The methods for the determination of impurities are discussed in Confidential Appendix D. Gas

chromatography method AL 27/78, used to determine the active ingredient, utilizes a 1.5 M glass column packed with 10% OV-210 on Chromosorb W-AW-DMCS and a thermal conductivity detector. Samples are dissolved in toluene and silylated with N,O-bis-trimethyl-silyl-acetamide for 20 minutes at 60 C. Di-(2-ethyl-hexyl)-phthalate is added as an internal standard.

The analytical enforcement methods submitted by Hoechst for the determination of endosulfan per se and its impurities do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the 96% T (EPA Reg. No. 8340-13) because methods were not submitted for impurities of potential toxicological concern identified in certification of ingredient limits at ≥0.1%, and validation data are insufficient. Additional information is required.

In response to the Guidance Document, Makhteshim submitted analytical methods (1983; MRID 00128662) for the determination of endosulfan per se and its impurities. The methods for the determination of the impurities are discussed in Confidential Appendix D. An isothermal gas chromatography method was submitted for the determination of endosulfan per se. Samples are dissolved in dichloromethane at 25 C. After 30 minutes samples are quantified by comparison to a calibrated external standard on a GC with a 60 cm glass column and a thermal conductivity detector.

The analytical enforcement methods submitted by Makhteshim for the determination of endosulfan per se and its impurities do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the 95% T (EPA Reg. No. 11678-5) and 35% FIs (EPA Reg. Nos. 11678-25 and 11678-26) because validation data were not submitted. Additional information is required.

No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Endosulfan Guidance Document dated April, 1982 identifies product-specific data requirements for all physical and chemical characteristics pertinent to the technical grade of the active ingredient and manufacturing-use products. The physical and chemical characteristics of the endosulfan purified active ingredient (PAI), technical grade of the active ingredient

(TGAI), and manufacturing-use products (MPs) are summarized in Table 2.

Data submitted by Hoechst (1983; MRIDs 00128657 and 00142995) for the 96% T (EPA Reg. No. 8340-13) satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-2 through 63-13, and 63-17) regarding color, physical state, odor, melting point, boiling point, density, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, stability, and storage stability. However, the registrant needs to define the first grade sample (PAI or TGAI) used in determination of vapor pressure. Current requirements for the technical product as an MP specify additional physical and chemical characteristics; therefore, data concerning the following additional characteristics are required for the Hoechst 96% T (EPA Reg. No. 8340-13): oxidizing/reducing action, explodability, and corrosiveness (Guideline Reference Nos. 63-14, 63-16, and 63-20). Additional data are required.

Data submitted by Makhteshim (1983; MRIDs 00128661 and 00128662) for the 95% T (EPA Reg. No. 11678-5) satisfy the corresponding requirements of 40 CFR §158.190 (Guideline Reference No. 63-2 through 63-19) regarding all physical/chemical properties except corrosion characteristics (Guideline Reference No. 63-20). Additional data are required.

Data submitted by Makhteshim (1983; MRID 00128650) for the 35% FI (EPA Reg. No. 11678-25) satisfy the corresponding requirements of 40 CFR §158.190 (Guideline Reference No. 63-2 through 63-20) regarding all physical/chemical properties of the manufacturing-use product.

No data were submitted for the Makhteshim 35% FI (EPA Reg. No. 11678-26) pertaining to physical/chemical characteristics. Manufacturing-use product data requirements regarding these topics remain outstanding for this product.

No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). The requirement for data concerning this product will be determined upon clarification of the source of the active ingredient in this product.

Table 2. Physical and chemical properties of the endosulfan purified active ingredient (PAI), technical grade of the active ingredient (TGAI), and manufacturing-use products (MPs).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; EPA Reg. No.; MRID)[a]
63-2. Color	**beige to dark brown** (96% T; TGAI; 8340-13; 00128657) **light brown to brown** (95% T; TGAI; 11678-5; 00128661) **tan** (35% FI; MP; 11678-25; 00128650)
63-3. Physical state	**flakes, with a tendency to agglomeration** (96% T; TGAI; 8340-13; 00128657) **solid** (95% T; TGAI; 11678-5; 00128661) **liquid** (35% FI; MP; 11678-25; 00128650)
63-4. Odor	**sulfur dioxide odor** (96% T; TGAI; 8340-13; 00128657) **slight SO_2 odor** (95% T; TGAI; 11678-5: 00128661) **specific aromatic odor** (35% FI; MP; 11678-25; 00128650)
63-5. Melting point	**80 C** [CIPAC MT 2, 1970 edition] (96% T; TGAI; 8340-13; 00128657) **70 to 100 C** [CIPAC MT 2, 1970 edition] (95% T; TGAI; 11678-5; 00128661)
63-6. Boiling point	**not required;** endosulfan technical is a solid at room temperature.
63-7. Density, bulk density, or specific gravity	**1.8 g/cm^3 at 20 C** [Hoechst test method for plant protection products No. 0016] (96% T; TGAI; 8340-13; 00128657) **1.745 at 20 C** (95% T; TGAI; 11678-5; 00128661) **1.06-1.08 at 20 C** (35% FI; MP; 11678-25; 00128650)

(Continued.)

Table 2. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; EPA Reg. No.; MRID or Jacket)[a]
63-8. Solubility	**not required;** data previously reviewed for Guidance Document (96% T; TGAI; 8340-13) (95% T; TGAI; 11678-5) (96% T; TGAI; 279-2306)
63-9. Vapor pressure	**6.2 x 10^{-6} Torr at 20 C** [Molecular Ray Method] (96% T; 1st grade; 8340-13; 00128657) **1 x 10 -5 mm Hg at 25 C** (95% T; PAI; 11678-5; 00128661)
63-10. Dissociation constant	**not required;** endosulfan is not an acid or base
63-11. Octanol/water partition coefficient	**P = 61200** [AL 35/79] (96% T; TGAI; 8340-13; 00128657) **K_{ow}=1.1 x 10^{5}** [Method CG 1400] (95% T; PAI; 11678-5; 00128661)
63-12. pH	**5.8 ± 1** (1% in distilled water) **6.0 ± 1** (10% in distilled water) (96% T; TGAI; 8340-13; 00128657) **pure endosulfan is neutral; technical grade may evolve some SO_2 fumes and react as an acid** (95% T; TGAI; 11678-5; 00128661) **neutral** (35% FI; MP; 11678-25; 00128650)
63-13. Stability	**decomposed by acids and bases; sensitive to moisture, iron and rust** (96% T; TGAI; 8340-13; 00128657) **prone to autocatalytical decomposition triggered by hydrogen or metallic ions, i.e iron; the technical product is** [redacted] to prevent decomposition (95% T; TGAI; 11678-5: 00128661).
63-14. Oxidizing or reducing action	**no oxidizing or reducing properties** (95% T; TGAI; 11678-5; 00128662) **not applicable** (35% FI; MP; 11678-25; 00128650)

(Continued.)

Table 2. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; EPA Reg. No.; MRID or Jacket)[a]
63-15. Flammability	**not required for solids** (96% T; 8340-13 and 95% T; 11678-5) **flash point >100 F** [closed cup test] (35% FI; MP; 11678-25; 00128650)
63-16. Explodability	**non-explosive** (95% T; TGAI; 11678-5; 00128662) (35% FI; MP; 11678-25; 00128650)
63-17. Storage stability	**stable for 2 years at room temperature; for 3 months at 50 C** [AL 17/80] (96% T; TGAI; 8340-13; 00142995) **stable for 1 year** (95% T; TGAI; 11678-5; 00128662) **stable for 1 year** (35% FI; MP; 11678-25; 00128650)
63-18. Viscosity	**not required for solids** (96% T 8340-13 and 95% T 11678-5) **1.3 ± 0.2 centipoises at 20 C** (35% FI; MP; 11678-25; 00128650)
63-19. Miscibility	**not required for solids** (96% T 8349-13 and 95% T 11678-5) **miscible with petroleum solvent** (35% FI; MP; 11678-25; 00128650)
63-20. Corrosiveness	**not corrosive** (35% FI; MP; 11678-25; 00128650)

[a] PAI = purified active ingredient. TGAI = technical grade of the active ingredient. MP = manufacturing-use product. FI = formulation intermediate. Hyphenated numbers represent EPA Registration Numbers. Eight-digit numbers are MRID documents from the Pesticide Document Management System (PDMS).

Product Chemistry Citations (used):

00128650 Makhteshim Beer-Sheva Chemical Works Ltd. (1983) Thionex 35 EC: End Use Product: [Chemistry Data]. (Compilation; unpublished study received May 31, 1983 under 11678-25; CDL:250400-A)

00128657 American Hoechst Corp. (1982) [Chemistry of Thiodan]. (Compilation; unpublished study received May 31, 1983 under 8340-13; CDL:250395-A)

00128661 Makhteshim Beer-Sheva Chemical Works, Ltd. (19??) Endosulfan Technical. (Compilation; unpublished study received May 31, 1983 under 11678-5; CDL:250396-A)

00128662 Makhteshim Beer-Sheva Chemical Works, Ltd. (1983) [Chemistry of Thionex (Endosulfan) Technical]. (Compilation; unpublished study received May 31, 1983 under 11678-5; CDL:250397-A)

00142995 Rexer, K.; Albrecht (1983) [Storage Stability Studies for Endosulfan Substance, Technical]: Bericht-Nr. WIR 0072 (31). Unpublished study prepared by Hoechst AG. 6 p.

00144958 Dehmer (1984) Possible Formation Routes of the Byproducts Contained in Technical Grade Endosulfan. Unpublished study prepared by Hoechst AG. 4 p.

40496601 Registration Dept. Makhteshim Chemical Works Ltd. (1987) Thionex (Endosulfan)--Product Chemistry Data: Laboratory Project ID: R-4773. Unpublished study. 37 p.

40623101 Dehmer; Kaiser (1987) Endosulfan Technical: Description of Beginning Materials and Manufacturing Process: Laboratory Project No. 87/2: A 36864. Unpublished compilation prepared by Hoechst Ag. 18 p.

40623102 Sarafin, R. (1987) HOE 002671 (Endosulfan): Discussion of the Formation of Impurities in the Technical Grade Substance: Laboratory Project No. (B) 179/87: A 36812. Unpublished compilation prepared by Hoechst Ag. 18 p.

40623103 Goerlitz, G. (1987) HOE 002671 (Endosulfan): Analysis for Polychlorinated Dibenzodioxins (PCDD) and Polychlorinated Dibenzofurans (PCDF): Laboratory Project No. (B) 189/87: A 36893. Unpublished compilation prepared by Hoechst Ag. 13 p.

[These MRIDs are referenced in a DEB memo but data are not reviewed in this Update document.]

40476501 Shuttleworth, J. (1987) Response to EPA Data Call In Notice for Product Chemistry Data Relating to Potential Formation

of Halogenated Dibenzo-p-Dioxin or Dibenzofuran Contaminants in Certain Active Ingredients: Endosulfan. Unpublished compilation prepared by FMC Corp. 20 p.

40476502 Shuttleworth, J. (1987) Response to EPA Data Call In Notice for Product Chemistry Data Relating to Potential Formation of Halogenated Dibenzo-p-Dioxin or Dibenzofuran Contaminants in Certain Active Ingredients: Endosulfan. Unpublished compilation prepared by FMC Corp. 18 p.

40476503 Shuttleworth, J. (1987) Response to EPA Data Call In Notice for Product Chemistry Data Relating to Potential Formation of Halogenated Dibenzo-p-Dioxin or Dibenzofuran Contaminants in Certain Active Ingredients: Endosulfan. Unpublished compilation prepared by FMC Corp. 18 p.

40476504 Shuttleworth, J. (1987) Response to EPA Data Call In Notice for Product Chemistry Data Relating to Potential Formation of Halogenated Dibenzo-p-Dioxin or Dibenzofuran Contaminated in Certain Active Ingredients: Endosulfan. Unpublished study prepared by FMC Corp. 20 p.

40476505 Shuttleworth, J. (1987) Response to EPA Data Call In Notice for Product Chemistry Data Relating to Potential Formation of Halogenated Dibenzo-p-Dioxin or Dibenzofuran Contaminants in Certain Active Ingredients: Endosulfan. Unpublished compilation prepared by FMC Corp. 22 p.

Product Chemistry Citations (not used):

[These MRIDs were not reviewed as they pertain to FI dioxin data; dioxin data have been submitted for the technical and are not required for the FI.]

40496301 Makhteshim Chemical Works Ltd. (1987) Thionex (Endosulfan) - Product Chemistry Data: R-4773. Unpublished study prepared by the Registration Dept. 9 p.

40496401 Registration Dept. Makhteshim Chemical Works Ltd. (1987) Thionex (Endosulfan)--Product Chemistry Data: Laboratory Project ID: R-4773. Unpublished study. 9 p.

[The following MRIDs pertain to end-use products or cancelled products.]

00128663 Makhteshim Beer-Sheva Chemical Works, Ltd. (1983) Endosulfan Registration Standard--End Use Product--Thionex (Endosulfan) 50 W. (Compilation; unpublished study received May 31, 1983 under 11678-42; CDL:250398-A)

00128846 FMC Corp. (1983) [Chemistry: Thiodan 50 WP Code 190]. (Compilation; unpublished study received Jun 1, 1983 under 279-1380; CDL:250423-A)

00129215 Velsicol Chemical Corp. (1977) [Chemistry: Endosulfan]. (Compilation; unpublished study received Jul 14, 1983 under 876-201; CDL:250726-A)

00139081 Hooker Chemical & Plastics Corp. (1976) [Chemistry of Endosulfan]. (Compilation; unpublished study received Mar 6, 1984 under 935-26; CDL:252567-A)

00141226 J. R. Simplot Co. (1980) [Analyses of Thiodan 2 EC Samples]. Unpublished compilation. 6 p.

00143220 Makhteshim Beer Sheva Chemical Works, Ltd. (19??) Endosulfan Registration Standard [for] Manufacturing Product Thionex ... 50 WP Unpublished compilation. 75 p.

00143792 FMC Corp. (19??) [Product Chemistry Data for Thiodan 50 WP]. Unpublished compilation. 2 p.

00144078 FMC Corp. (1984) Endosulfan Reregistration Thiodan 50 WP ... Product Chemistry ... Addendum. Unpublished compilation. 3 p.

00147060 Smith, H. (1985) Product Chemistry: [Thio-Gard 3 Flowable]. Unpublished study. 13 p.

00148158 FMC Corp. (1985) Product Chemistry --Thiodan 3 EC Insecticide. Unpublished compilation. 22 p.

00153019 Agway, Inc. (1984) [Thiodan Reregistration and Thiodan Formulations for EPA Stability Studies]. Unpublished study. 4 p.

00157520 Tucker, D., comp. (1986) Product Chemistry in Support of Registration of Endosulfan 50 W.P. Unpublished compilation prepared by Micro-Flo Co. 52 p.

00157700 Tucker, D.; comp. (1986) Product Chemistry...Endosulfan 3EC. Unpublished compilation prepared by Micro-Flo Co. 43 p.

00160011 Grypa, R. (1986) Letter sent to W. Landis dated May 30, 1986: Dragon Thiodan Insect Spray: [Storage stability data]. Prepared by Agway Inc. 1 p.

00160095 Tucker, D., comp. (1986) Product Chemistry: SA-50 Brand Thiodan 4 Dust. Unpublished compilation. 45 p.

40273701 Tucker, D. (1987) 12 Month Storage Stability Study for Thiodan 4% Dust: Lab Project ID: SOUTH-AG THIO4D-EU-1. Unpublished study prepared by Chempax. 5 p.

40496201 Makhteshim Chemical Works Ltd. (1987) Thionex (Endosulfan) - Product Chemistry Data: R-4773. Unpublished study prepared by the Registration Dept. 9 p.

40496501 Registration Dept. Makhteshim Chemical Works Ltd. (1987) Thionex (Endosulfan)--Product Chemistry Data: Laboratory Project ID: R-4773. Unpublished study. 9 p.

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

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Partially	00128650 00128657 00128662 00144958 40496601	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	00128650 00128662 00144958 40496601	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	TGAI	Partially	00128662	Yes[6]
Physical and Chemical Characteristics[7]				
63-2. Color	TGAI	Partially	00128650 00128657 00128661	Yes[8]
63-3. Physical State	TGAI	Partially	00128650 00128657 00128661	Yes[8, 11]
63-4. Odor	TGAI	Partially	00128650 00128657 00128661	Yes[8, 11]
63-5. Melting Point	TGAI	Partially	00128657 00128661	Yes[8, 11]
63-6. Boiling Point	TGAI	N/A	N/A	No[9]
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Partially	00128650 00128657 00128661	Yes[8, 11]
63-8. Solubility	TGAI or PAI	Yes	N/A	No[10]
63-9. Vapor Pressure	TGAI or PAI	Partially	00128657 00128661	Yes[8, 11,11]
63-10. Dissociation Constant	TGAI or PAI	N/A	N/A	No[12]

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
63-11. Octanol/Water Partitioning Coefficient	PAI	Partially	00128657 00128661	Yes[8, 11]
63-12. pH	TGAI	Partially	00128650 00128657 00128661	Yes[8, 11]
63-13. Stability	TGAI	Partially	00128657 00128661	Yes[8, 11]
Other Requirements: 64-1. Submittal of Samples	N/A	N/A	N/A	No

1. The following requirements pertain to Hoechst Celanese Corp. 96% T (EPA Reg. No. 8340-13), Makhteshim Chemical Works 95% T, 35% EC (FI), and 35% WP (FI) (EPA Reg. Nos. 11678-5, 11678-25, and 11678-26, respectively), and the FMC Corp. 96% T (EPA Reg. No. 279-2306). We note that there is a discrepancy between the CSF and more recent company correspondence regarding the source of the TGAI in the FMC 96% T (EPA Reg. No. 279-2306). The recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Endosulfan Manufacturing-Use Products".

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

3. Underlining indicates documents that have been reviewed in this Update document.

4. Hoechst and Makhteshim have responded to Guidance Document requirements, although additional data are required. For the Hoechst 96% T (EPA Reg. No. 8340-13), the following data are required: (i) a statement as to whether the process is batch or continuous; (ii) the duration of each step and of the entire process; (iii) the relative amounts of the materials used; (iv) a description of the manufacturing equipment; (v) a complete description of the reaction conditions controlled (e.g. pH, pressure) during each step of the

TABLE A. (Continued).

process; and (vi) a description of the sampling regimen and quality control procedures necessary to assure product consistency. For the Makhteshim 95% T (EPA Reg. No. 11678-5), the following information is required: (i) a statement as to whether the process is batch or continuous; (ii) the duration of each step and of the entire process; (iii) a complete description of the reaction conditions controlled (e.g. pH, pressure) during each step of the process; (iv) a complete description of purification procedures including solvent recycling; and (v) a description of the sampling regimen and quality control procedures necessary to assure product consistency. In addition, Makhteshim must submit data for the 95% T to regarding starting materials and manufacturing process to satisfy the dioxin Data Call-in Notice of 6/9/87. For their 35% FI (EPA Reg. No. 11678-25), Makhteshim must submit additional information regarding a description of the manufacturing process; including mixing conditions (pH, temperature), addition order of ingredients, duration of the process, and quality control procedures. For the Makhteshim 35% FI (EPA Reg. No. 11678-26), all data pertaining to starting materials and the formulation process are required. No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

5. Hoechst and Makhteshim have submitted data in response to the Guidnace Document; however, additional data are required. For the Hoechst 96% T (EPA Reg. No.8340-13) additional information is required regarding (i) the possible degradation of the ingredients in the product after its production but prior to use; (ii) post production reactions between ingredients in the product; (iii) the possible migration of components of packaging materials into the pesticide; (iv) the possible carryover of contaminants from production equipment used to produce other products; and (v) process control, purification procedures and quality control measures used to produce the product. Makhteshim must submit, for their 95% T (EPA Reg. No. 11678-5), additional data concerning (i) the formation of all the impurities listed on the CSF at ≥0.1%; (ii) the possible migration of components of packaging materials into the pesticide; (iii) the possible carryover of contaminants from use of production equipment used to produce other products or substances; (iv) the impurities in the starting materials; and (v) potential impurities arising from the process control, purification procedures and quality control measures used to produce the product. In addition, additional information is required for the Makhteshim 95% T (EPA Reg. No. 11678-5) regarding the formation of impurities to satisfy the 6/9/87 dioxin Data Call-in Notice. For the 35% FI (EPA Reg. No. 11678-25), Makhteshim must submit a discussion of possible impurities from (i) the degradation of the ingredients in the product after its production but prior to use; (ii) post production reactions between ingredients in the product; (iii) the migration of components of packaging materials into the pesticide; (iv) the carryover of contaminants from use of production equipment used to produce other products or substances; and (v) the process control, purification procedures and quality control measures used to produce the product. All data

TABLE A. (Continued).

pertaining to discussion of formation of impurities are required for the Makhteshim 35% FI (EPA Reg. No. 11678-26). No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

6. Makhteshim responded to the Guidance Document with data regarding preliminary analysis; however they must submit raw data for the active ingredient and the impurities, the mean and standard deviation for all ingredients, and the analytical methods used (including validation data). Data concerning preliminary analysis are required for the Hoechst 96% T (EPA Reg. No. 8340-13). No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

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

8. FMC has not responded to the data requirements for the 96% T. If the requested updated CSF indicates that this is a repackaged product, no additional data are required for this topic.

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

10. Data were submitted and found adequate at the time of the Guidance Document.

11. Hoechst must define the test substance, "first grade sample", for the 96% T.

12. Data on dissociation constant are not required since the PAI is not an acid or base.

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

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Composition	MP	Partially	00128650 00128657 00128662 40496601	Yes[4]
61-2. Beginning Materials & Production/Formulation Process	MP	Partially	00128650 00128657 00128662 00144958 40496601	Yes[5]
61-3. Formation of Impurities	MP	Partially	00144958 00128650 00128662 40496601	Yes[6]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	MP	Partially	00128662	Yes[7]
62-2. Certified Limits	MP	Partially	00128650 00128657 00128662	Yes[8]
62-3. Enforcement Analytical Methods	MP	Partially	00128657 00128662	Yes[9]
Physical and Chemical Characteristics[10]				
63-2. Color	MP	Partially	00128650 00128657 00128661	Yes[11]
63-3. Physical State	MP	Partially	00128650 00128657 00128661	Yes[11]

TABLE B. (Continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
63-4. Odor	MP	Partially	00128650 00128657 00128661	Yes[11]
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	00128650 00128657 00128661	Yes[11]
63-12. pH	MP	Partially	00128650 00128657 00128661	Yes[11]
62-14. Oxidizing or Reducing Action	MP	Partially	00128650 00128662	Yes[11,12]
62-15. Flammability	MP	Yes	00128650	No[13]
63-16. Explodability	MP	Partially	00128650 00128662	Yes[11,14]
63-17. Storage Stability	MP	Partially	00128650 00128662 00142995	Yes[11]
63-18. Viscosity	MP	Yes	00128650	No[15]
63-19. Miscibility	MP	Yes	00128650	No[16]
63-20. Corrosion Characteristics	MP	Partially	00128650	Yes[11,17]
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

1. The following requirements pertain to Hoechst Celanese Corp. 96% T (EPA Reg. No. 8340-13), Makhteshim Chemical Works 95% T, 35% EC (FI), and 35% WP (FI) (EPA Reg. Nos. 11678-5, 11678-25, and 11678-26, respectively), and FMC Corp. 96% T (EPA Reg. No. 279-2306). We note that FMC has listed 3 suppliers on the CSF for its 96% technical product; if FMC is producing the technical endosulfan, product chemistry data are required for all topics. If the FMC technical product is produced by Hoechst and Makhteshim then their submitted product chemistry data may be applied to the reregistration of the FMC 96% T. Additional data

TABLE B. (Continued).

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

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

3. Underlining indicates documents that have been reviewed in this Update document.

4. Hoechst and Mahkteshim have responded to the Guidance Document for their products listed in footnote 1; however, additional data are required. For each product, a revised CSF is required, identifying impurities and inert ingredients, providing niminal concentrations for the listed components (for the FIs, the nominal concentration of the active ingredient must be based on the concentration in the source product), the source of the active ingredient), and whether the product represents a repackaging of another registered product. If the CSF indicates an alternate formulation, information on the basic formulation must be provided. Updated CSFs must be submitted on EPA form 8570-4 (Rev. 2-85).

5. Hoechst and Makhteshim have responded to Guidance Document requirements, although additional data are required. For the Hoechst 96% T (EPA Reg. No. 8340-13), the following data are required: (i) a statement as to whether the process is batch or continuous; (ii) the duration of each step and of the entire process; (iii) the relative amounts of the materials used; (iv) a description of the manufacturing equipment; (v) a complete description of the reaction conditions controlled (e.g. pH, pressure) during each step of the process; and (vi) a description of the sampling regimen and quality control procedures necessary to assure product consistency. For the Makhteshim 95% T (EPA Reg. No. 11678-5), the following information is required: (i) a statement as to whether the process is batch or continuous; (ii) the duration of each step and of the entire process; (iii) a complete description of the reaction conditions controlled (e.g. pH, pressure) during each step of the process; (iv) a complete description of purification procedures including solvent recycling; and (v) a description of the sampling regimen and quality control procedures necessary to assure product consistency. In addition, Makhteshim must submit data for the 95% T to regarding starting materials and manufacturing process to satisfy the dioxin Data Call-in Notice of 6/9/87. For their 35% FI (EPA Reg. No. 11678-25), Makhteshim must submit additional information regarding a description of the manufacturing process; including mixing conditions (pH, temperature), addition order of ingredients, duration of the process, and quality control procedures. For the Makhteshim 35% FI (EPA Reg. No. 11678-26), all data pertaining to starting materials and the formulation process are required. No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of

TABLE B. (Continued).

the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

6. Hoechst and Makhteshim have submitted data in response to the Guidnace Document; however, additional data are required. For the Hoechst 96% T (EPA Reg. No.8340-13) additional information is required regarding (i) the possible degradation of the ingredients in the product after its production but prior to use; (ii) post production reactions between ingredients in the product; (iii) the possible migration of components of packaging materials into the pesticide; (iv) the possible carryover of contaminants from production equipment used to produce other products; and (v) process control, purification procedures and quality control measures used to produce the product. Makhteshim must submit, for their 95% T (EPA Reg. No. 11678-5), additional data concerning (i) the formation of all the impurities listed on the CSF at ≥0.1%; (ii) the possible migration of components of packaging materials into the pesticide; (iii) the possible carryover of contaminants from use of production equipment used to produce other products or substances; (iv) the impurities in the starting materials; and (v) potential impurities arising from the process control, purification procedures and quality control measures used to produce the product. In addition, additional information is required for the Makhteshim 95% T (EPA Reg. No. 11678-5) regarding the formation of impurities to satisfy the 6/9/87 dioxin Data Call-in Notice. For the 35% FI (EPA Reg. No. 11678-25), Makhteshim must submit a discussion of possible impurities from (i) the degradation of the ingredients in the product after its production but prior to use; (ii) post production reactions between ingredients in the product; (iii) the migration of components of packaging materials into the pesticide; (iv) the carryover of contaminants from use of production equipment used to produce other products or substances; and (v) the process control, purification procedures and quality control measures used to produce the product. All data pertaining to discussion of formation of impurities are required for the Makhteshim 35% FI (EPA Reg. No. 11678-26). No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

7. Makhteshim responded to the Guidance Document with data regarding preliminary analysis; however they must submit raw data for the active ingredient and the impurities, the mean and standard deviation for all ingredients, and the analytical methods used (including validation data). Data concerning preliminary analysis are required for the Hoechst 96% T (EPA Reg. No. 8340-13). No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI

TABLE B. (Continued).

obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

8. All the registrants have responded to the data requirements for their products listed in footnote 1, however updated CSFs are required for all products and all certifications need to be resubmitted on EPA form 8570-4 (Rev. 2-85). For each product, upper and lower certified limits must be proposed for each active and inert ingredient, if such limits would differ from the standard certified limits determined by the Agency according to 40 CFR §158.175(b)(2). Certified limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production. The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used.

9. Hoechst and Mahkteshim have responded to the Guidance Document; however, Hoescht did not provide methods for impurities and Mahkteshim's methods were insufficiently validated. Additional data are required. Enforcement analytical methods are required for the active ingredient and all impurities of toxocological concern, and complete valiidation data must be submitted. No data were submitted for the FMC 96% T (EPA Reg. No. 279-2306). Although the available CSF lists FMC as a producer of the TGAI, more recent correspondence from FMC to the Agency indicates that the FMC product represents a repackaging of the TGAI obtained from another producer. Unless the updated CSF requested lists FMC as a producer, no additional data are required of FMC for this product.

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

11. FMC has not responded to the data requirements for the 96% T. If the requested updated CSF indicates that this is a repackaged product, no additional data are required for this topic. Mahkteshim has not

TABLE B. (Continued).

responded for their 35% FI (EPA Reg. No. 11678-26); data concerning this topic are required for this product.

12. Hoechst has not responded to the data requirements for the 96% T; data are required on oxidizing/reducing potential if the product contains an oxidizing or reducing agent.

13. Data are not required on flammability for the endosulfan products that do not contain combustible liquids.

14. Hoechst has not responded to data requirements for the 96% T; data are required if the product is potentially explosive.

15. Data on viscosity are not required for the endosulfan products that are solids at room temperature.

16. Data on miscibility are not required for the endosulfan products that are solids.

17. Hoechst and Makhteshim have not responded to data requirements for their technical products listed in footnote 1; data are required as the technical is a manufacturing-use product.