US EPA ARCHIVE DOCUMENT

L. ROSSI
3-5-91

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 5 1991

MAR 5 1993

MEMORANDUM

SUBJECT: Response to the Trifluralin Reregistration Standard: Product Chemistry Data (MRID's # 40446902, 40453302, 40453303, 40453402, 40453403 ,41306701, 40453404, 40454701, 40851401, 40674301, 40674302 and 41025601. CBRS #'s 7175, 7176 and 7177.)

FROM: R. B. Perfetti, Ph.D., Chemist
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 reviews of product chemistry data submitted by DowElanco, Industria Prodotti Chimici, S.p.A. and Agan Chemical Manufacturers, Ltd. in response to the trifluralin 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 Trifluralin Product Chemistry Data.

Attachment 2 : Confidential Appendices A and B for the DowElanco Product and Confidential Appendices A, B, C, D, and E for the Agan Chemical Manufacturers, Ltd. Product.

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

cc: With Attachment 1: Circulation (7).

cc: Without Attachment: P. Fenner-Crisp (HED) and RF.

DYNAMAC
CORPORATION

Final Report

TRIFLURALIN (DEB No. 7175) Task 4: Registrant's Response to Product Chemistry Data Requirements

December 21, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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

3

TRIFLURALIN (DEB NO. 7175)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the Trifluralin Guidance Document, dated 4/87 **DowElanco** has submitted five volumes of product chemistry data (DEB No. 7175; 1987; MRIDs 40453302, 40453303, 40453402, 40453403, and 40453404) for the 95% trifluralin technical (T) formulation (EPA Reg. No. 62719-99). These data and our conclusions are discussed below.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

DowElanco has not provided information pertaining to product identity and disclosure of ingredients for the 95% T (EPA Reg. No. 62719-99). Guidance Document data requirements remain outstanding for this topic.

61-2. Description of Starting Materials and Manufacturing Process

DowElanco (1987; MRID 40453302) has submitted the names and addresses of the suppliers of starting materials along with their specifications, and a description of the manufacturing process for the 95% T product. A discussion of the current manufacturing process is given in Confidential Appendix A. These data satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the production process for the **DowElanco** 95% T (EPA Reg. No. 62719-99).

61-3. Discussion of Formation of Impurities

DowElanco (1987; MRID 40453302) has submitted a discussion of impurities formed during the production of the 95% T product. The discussion (see Confidential Appendix B) does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the 95% T (EPA Reg. No. 62719-99) because a discussion was not presented regarding the possible degradation of ingredients after production, post-production reactions between ingredients, and possible contamination from packaging materials.

4

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

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

DowElanco has not provided information pertaining to preliminary analysis, certification of limits, or enforcement analytical methods for the 95% T (EPA Reg. No. 62719-99). Guidance Document data requirements remain outstanding for these topics.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical and chemical characteristics for the 95% T (EPA Reg. No. 62719-99) have been submitted by **DowElanco** (1987; MRIDs 40453303, 40453402, 40453403, and 40453404). These properties are presented in Table 1. Data requirements remain outstanding for melting point, dissociation constant, octanol/water partition coefficient, stability, storage stability, and corrosion characteristics (Guideline Reference Nos. 63-5, 63-10, 63-11, 63-13, 63-17, and 63-20). In addition we note that two different values were reported for density (Guideline Reference No. 63-7); the registrant must address this matter.

Table 1. Physical and chemical properties of the **DowElanco** 95% T (EPA Reg. No. 62719-99) purified active ingredient (PAI) and technical grade of the active ingredient (TGAI).

Guidelines Reference No., 40 CFR §158.190; Name of Property		**Description** [Method] (Substrate; MRID)
63-2.	Color	**bright orange** (TGAI; 40453303)
63-3.	Physical state	**crystalline solid** (TGAI; 40453303)
63-4.	Odor	**mild aromatic odor** (TGAI; 40453303))
63-5.	Melting point	none submitted[a]
63-6	Boiling point	**N/A; TGAI is a solid**
63-7.	Density, bulk density, or specific gravity	**1.224-1.256 g/cc** [solidified molten material] (TGAI; 40453303) **0.600 g/cc** [Eli Lilly Lab Procedure GP 7011] (TGAI; 40453402)

(Continued.)

5

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property		**Description** [Method] (Substrate; MRID)
63-8.	Solubility	**Solvent Solubility at 25 C** **water 0.284 µg/ml** **methanol 3.3-4.0 g/100 ml** **hexane 5.0-6.7 g/100 ml** **ethyl acetate, acetone, dichloromethane, chloroform, acetonitrile, and toluene >100 g/100 ml** [saturation column technique] (TGAI; 40453403)
63-9.	Vapor pressure	**1.03×10^{-4} mm Hg** [GC headspace] (TGAI; 40453404)
63-10.	Dissociation constant	none submitted[a]
63-11.	Octanol/water partition coefficient	none submitted[a]
63-12.	pH	**5.6** [10% slurry in distilled water with a pH of 6.4] (TGAI; 40453303)
63-13.	Stability	none submitted[a]
63-14.	Oxidizing/ reducing action	**no gas evolution or temperature increase in ammonium dihydrogenphosphate, potassium permanganate, and powdered zinc** [Reference AM-AA-CA-FO14-AA-659] (TGAI; 40453303)
63-15.	Flammability	**N/A; product is a solid**
63-16.	Explodability	**not impact sensitive** [Reference AM-AA-CA-FO19-AA-659] (TGAI; 40453303)
63-17.	Storage Stability	study started 7/13/87, will be reported later (40453303)
63-18.	Viscosity	**N/A; product is a solid**
63-19.	Miscibility	**N/A; product is a solid**

(Continued.)

6

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	**Description** [Method] (Substrate; MRID)
63-20. Corrosion Characteristics	studies in conjunction with storage stability, will be reported later (40453303)

[a] The registrant has not submitted data for certain physical and chemical properties claiming that data are "not required for manufacturing-use products"; however, information pertaining to these characteristics is required as this product is a technical.

7

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TRIFLURALIN 95% TECHNICAL (DOWELANCO) 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 & Production Process	TGAI	R		X	40453302
61-3. Formation of Impurities	TGAI	R	X[3]		40453302
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR	X		
Physical and Chemical Characteristics					
63-2. Color	TGAI	R		X	40453303
63-3. Physical State	TGAI	R		X	40453303
63-4. Odor	TGAI	R		X	40453303
63-5. Melting Point	TGAI	R	X[4]		
63-6. Boiling Point	TGAI	R		X[5]	
63-7. Density/Specific Gravity	TGAI	R	X[6]		40453303, 40453402
63-8. Solubility	TGAI or PAI	R		X	40453403
63-9. Vapor pressure	TGAI or PAI	R		X	40453404
63-10. Dissociation Constant	TGAI or PAI	R	X[7]		
63-11. Octanol/Water Partition Coefficient	PAI	CR	X[8]		
63-12. pH	TGAI	CR		X	40453303
63-13. Stability	TGAI	R	X		
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[9]	

(Continued, footnotes follow)

TABLE A. (Continued).

1. Data requirements pertain to the DowElanco 95% T (EPA Reg. No. 62719-99). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Trifluralin 95% Technical (DowElanco) 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. A discussion must be provided regarding the possible degradation of ingredients after production, post-production reactions between ingredients, and possible contamination from packaging materials.

4. Data on melting point are required if the technical chemical is a solid at room temperature.

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

6. The registrant must explain why two different values for density were reported.

7. Data on dissociation constant are required if the PAI is an acid or a base.

8. Data on octanol/water partition coefficient are required if the technical chemical is organic and nonpolar.

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

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE TRIFLURALIN 95% TECHNICAL (DOWELANCO) MANUFACTURING-USE PRODUCT.[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		
61-2. Beginning Materials & Production/Formulation Process	MP	R		X	40453302
61-3. Formation of Impurities	MP	R	X[3]		40453302
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	CR	X		
62-2. Certified Limits	MP	R	X		
62-3. Enforcement Method	MP	R	X		
Physical and Chemical Characteristics					
63-2. Color	MP	R		X	40453303
63-3. Physical State	MP	R		X	40453303
63-4. Odor	MP	R		X	40453303
63-7. Density/Specific Gravity	MP	R	X[4]		40453303, 40453402
63-12. pH	MP	CR		X	40453303
62-14. Oxidizing/Reducing Action	MP	CR		X	40453303
62-15. Flammability	MP	CR		X[5]	
63-16. Explodability	MP	R		X	40453303
63-17. Storage Stability	MP	R	X[6]		40453303
63-18. Viscosity	MP	CR		X[5]	
63-19. Miscibility	MP	CR		X[5]	
63-20. Corrosion Characteristics	MP	R	X[7]		40453303

(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.)
Other Requirements:					
64-1. Submittal of Samples	MP	CR		X[8]	

1. Data pertain to the DowElanco 95% T (EPA Reg. No. 62719-99). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Trifluralin 95% Technical (DowElanco) Technical Grade of the Active Ingredient."

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

3. A discussion must be provided regarding the possible degradation of ingredients after production, post-production reactions between ingredients, and possible contamination from packaging materials.

4. The registrant must explain why two different values for density were reported.

5. Data are not required since the product is a solid at room temperature.

6. The registrant has stated that a storage stability study was started on 7/13/87, and that data will be reported later.

7. The registrant has stated that a study was started in conjunction with a storage stability study, and that data will be reported later.

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

DYNAMAC
CORPORATION

Final Report

TRIFLURALIN (DEB No. 7176) Task 4: Registrant's Response to Product Chemistry Data Requirements

December 21, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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

12

TRIFLURALIN (DEB NO. 7176)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the Trifluralin Guidance Document dated 4/87, **Industria Prodotti Chimici, S.p.A.** has submitted one volume of product chemistry data (1987; MRID 40446902, DEB No. 7176) for the 96% trifluralin technical (T) product (EPA Reg. No. 33660-3).

These data and our conclusions are discussed below.

PRODUCT IDENTITY AND COMPOSITION

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

Industria Prodotti Chimici, S.p.A. has not provided information pertaining to the product identity and disclosure of ingredients, starting materials and manufacturing process, or discussion of the formation of impurities for the 96% T (EPA Reg. No. 33660-3). Guidance Document data requirements remain outstanding for these topics.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

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

Industria Prodotti Chimici, S.p.A. has not provided information pertaining to preliminary analysis, certification of limits, or enforcement analytical methods for the 96% T (EPA Reg. No. 33660-3). Guidance Document data requirements remain outstanding for these topics.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical and chemical characteristics for the 96% T (EPA Reg. No. 33660-3) have been submitted by **Industria Prodotti Chimici, S.p.A.** (1987; MRID 40446902). These properties are presented in Table 1. No data were presented for storage stability (Guideline Reference No. 63-17). In addition, the data submitted for corrosion characteristics are not adequate; data must reflect the product's corrosive effects at full strength on materials used to package and store the product.

Table 1. Physical and chemical properties of the **Industria Prodotti Chimici, S.p.A.** 96% T (EPA Reg. No. 33660-3) purified active ingredient (PAI) and technical grade of the active ingredient (TGAI). Data are from MRID 40446902.

Guidelines Reference No., 40 CFR §158.190; Name of Property		**Description** [Method] (Substrate)
63-2.	Color	**orange-red** (TGAI)
63-3.	Physical state	**crystalline solid** (TGAI)
63-4.	Odor	**odorless** (TGAI)
63-5.	Melting point	**45-48 C** [CIPAC MT 2] (TGAI)
63-6	Boiling point	**N/A; TGAI is a solid**
63-7.	Density, bulk density, or specific gravity	**1.126 g/ml** [CIPAC MT 3.2.1] (PAI)
63-8.	Solubility	**Solvent — Solubility at 20 C** **water — 10^{-4} g/100 ml** **acetone — 32 g/100 ml** **xylene — 48 g/100 ml** [OECD 105] (TGAI)
63-9.	Vapor pressure	**1.27×10^{-4} mm Hg** [OECD Guidelines, section 1, number 104] (PAI)
63-10.	Dissociation constant	**does not dissociate** [conductivity] (PAI)

(Continued.)

14

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	**Description** [Method] (Substrate)
63-11. Octanol/water partition coefficient	**p = 3.33 x 10^3** [OECD 112] (PAI)
63-12. pH	**6-7** [ASTM E 70-74] (TGAI)
63-13. Stability	**stable in acid and alkaline medium; decomposes when exposed to sunlight; slowly degrades at high temperatures.** [GC] (TGAI)
63-14. Oxidizing/ reducing action	**no temperature increase or product decomposition in water, CO_2, iron, and zinc** [Federal Register 44, number 53, page 16267] (TGAI)
63-15. Flammability	**N/A; product is a solid**
63-16. Explodability	**not sensitive to impact** [UN document ST/SG/AC.10/11, Test 3(a)(ii)] (TGAI)
63-17. Storage Stability	test is under development
63-18. Viscosity	**N/A; product is a solid**
63-19. Miscibility	**N/A; product is a solid**
63-20. Corrosion Characteristics	**20% solution non-corrosive to iron foils** [ASTM G 31-72] (TGAI)

15

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TRIFLURALIN 96% TECHNICAL (INDUSTRIA PRODOTTI CHIMICI, S.p.A.) 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 & Production Process	TGAI	R	X		
61-3. Formation of Impurities	TGAI	R	X		
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR	X		
Physical and Chemical Characteristics					
63-2. Color	TGAI	R		X	40446902
63-3. Physical State	TGAI	R		X	40446902
63-4. Odor	TGAI	R		X	40446902
63-5. Melting Point	TGAI	R		X	40446902
63-6. Boiling Point	TGAI	R		X[3]	
63-7. Density/Specific Gravity	TGAI	R		X	40446902
63-8. Solubility	TGAI or PAI	R		X	40446902
63-9. Vapor pressure	TGAI or PAI	R		X	40446902
63-10. Dissociation Constant	TGAI or PAI	R		X	40446902
63-11. Octanol/Water Partition Coefficient	PAI	CR		X	40446902
63-12. pH	TGAI	CR		X	40446902
63-13. Stability	TGAI	R		X	40446902
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[4]	

TABLE A. (Continued).

1. Data requirements pertain to the INDUSTRIA PRODOTTI CHIMICI, S.p.A. 96% T (EPA Reg. No. 33660-3). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Trifluralin 96% Technical (INDUSTRIA PRODOTTI CHIMICI, S.p.A.) 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. Data on boiling point are not required because the technical chemical is a solid at room temperature.

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

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE TRIFLURALIN 96% TECHNICAL (INDUSTRIA PRODOTTI CHIMICI, S.p.A.) MANUFACTURING-USE PRODUCT.[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		
61-2. Beginning Materials & Production/Formulation Process	MP	R	X		
61-3. Formation of Impurities	MP	R	X		
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	CR	X		
62-2. Certified Limits	MP	R	X		
62-3. Enforcement Method	MP	R	X		
Physical and Chemical Characteristics					
63-2. Color	MP	R		X	40446902
63-3. Physical State	MP	R		X	40446902
63-4. Odor	MP	R		X	40446902
63-7. Density/Specific Gravity	MP	R		X	40446902
63-12. pH	MP	CR		X	40446902
62-14. Oxidizing/Reducing Action	MP	CR		X	40446902
62-15. Flammability	MP	CR		X[3]	
63-16. Explodability	MP	R		X	40446902
63-17. Storage Stability	MP	R	X[4]		40446902
63-18. Viscosity	MP	CR		X[3]	
63-19. Miscibility	MP	CR		X[3]	
63-20. Corrosion Characteristics	MP	R	X[5]		40446902

(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.)
Other Requirements:					
64-1. Submittal of Samples	MP	CR		X[6]	

1. Data requirements pertain to the INDUSTRIA PRODOTTI CHIMICI, S.p.A. 96% T (EPA Reg. No. 33660-3). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Trifluralin 96% Technical (INDUSTRIA PRODOTTI CHIMICI, S.p.A.) Technical Grade of the Active Ingredient."

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

3. Data are not required because the product is a solid at room temperature.

4. The registrant has stated that the test is under development.

5. Data are required reflecting the corrosive effects of the product <u>at full strength</u> on materials used for packaging and storing.

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

DYNAMAC
CORPORATION

Final Report

TRIFLURALIN (DEB No. 7177) Task 4: Registrant's Response to Product Chemistry Data Requirements

December 21, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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

30

TRIFLURALIN (DEB No. 7177)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the Trifluralin Guidance Document, dated 4/87 **Agan** Chemical Manufacturers, Ltd. has submitted one volume of product chemistry data (1987; MRID 40454701, DEB No. 7177) for the 98% trifluralin technical (T) formulation (EPA Reg. No. 11603-13).

These data and our conclusions are discussed below.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

Agan has submitted product identity data and a confidential statement of nominal composition for the 98% T (EPA Reg. No. 11603-13). Data are presented in Confidential Appendix A, and satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition for the Agan 98% T (EPA Reg. No. 11603-13).

61-2. Description of Starting Materials and Manufacturing Process

Agan has submitted the names and addresses of the suppliers of starting materials along with their specifications, and a description of the manufacturing process for the 98% T product. A discussion of the current manufacturing process is given in Confidential Appendix B. These data satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the production process for the **Agan** 98% T (EPA Reg. No. 11603-13).

61-3. Discussion of Formation of Impurities

Agan has submitted a discussion of impurities formed during the production of the 98% T product. The information (see Confidential Appendix C) does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities in the 98% T (EPA Reg. No. 11603-13) because a discussion was not presented regarding the possible degradation of ingredients after production, post-production reactions between ingredients, and possible contamination from packaging materials.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

Agan has provided preliminary analysis of five batches of the 98% T (EPA Reg. No. 11603-13) which are presented in Confidential Appendix D. These data do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the **Agan** 98% T (EPA Reg. No. 11603-13) because preliminary analysis for nitrosamines must be conducted on six samples from one representative batch of the 98% T collected immediately after production (two samples), three months after production (two samples), and six months after production (two samples). Additional data are required.

62-2. Certification of Limits

Agan has submitted lower and upper certified limits for the active ingredient and upper limits for the impurities of the 98% T (EPA Reg. No. 11603-13). These data are presented in Confidential Appendix A and do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the **Agan** 98% T (EPA Reg. No. 11603-13) because the upper certified limit for one impurity is exceeded by its nominal concentration. Additional data are required. In addition, the registrant must submit these certifications along with nominal concentrations on EPA Form 8570-4 (Rev 4-85).

62-3. Enforcement Analytical Methods

Agan has submitted analytical methods for the determination of the impurities and nitrosamines in the 98% T (EPA Reg. No. 11603-13); these methods are discussed in Confidential Appendix E.

[redacted]

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the **Agan** 98% T (EPA Reg. No. 11603-13) because complete validation data must be

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

submitted for analytical methods used to determine the active ingredient, impurities, and nitrosamines.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical and chemical characteristics for the 98% T (EPA Reg. No. 11603-13) have been submitted by **Agan**. These properties are presented in Table 1. No data were presented for dissociation constant, oxidizing/reducing action, explodability, storage stability, and corrosion characteristics (Guideline Reference Nos. 63-10, -14, -16, -17, and -20). These characteristics are required since the 98% T serves as a manufacturing-use product. In addition, data submitted for stability (Guideline Reference No. 63-13) are incomplete; the methods and storage conditions are required.

Table 1. Physical and chemical properties of the **Agan** 98% T (EPA Reg. No. 11603-13) purified active ingredient (PAI) and technical grade of the active ingredient (TGAI). Data are from MRID 40454701.

Guidelines Reference No., 40 CFR §158.190; Name of Property		**Description** [Method] (Substrate)
63-2.	Color	**orange** (TGAI)
63-3.	Physical state	**crystalline solid** (TGAI)
63-4.	Odor	**characteristic of organics** (TGAI)
63-5.	Melting point	**42-48 C** (TGAI) **48.5-49 C** (PAI)
63-6	Boiling point	**N/A; TGAI is a solid**
63-7.	Density, bulk density, or specific gravity	**1.30 g/cm^3** (TGAI)
63-8.	Solubility	

Solvent	Solubility at 25 C
water	0.2 ppm at pH 5
	0.2 ppm at pH 7
	0.3 ppm at pH 9
acetone	40 g/100 ml (20 C)
dioxane	83 g/100 ml
hexane	>50 g/100 ml
methanol	2 g/100 ml
xylene	81 g/100 ml

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Substrate)
63-8. Solubility (Cont'd.)	**dimethylformamide 82 g/100 ml** **methyl cellosolve 44 g/100 ml** **methyl ethyl ketone 88 g/100 ml** [EPA Method GC-1500 8/82] (PAI)
63-9. Vapor pressure	**48.5×10^{-6} mm Hg** (TGAI) **9.13×10^{-5} mm Hg** [Protocol 121/87] (PAI)
63-10. Dissociation constant	not submitted
63-11. Octanol/water partition coefficient	**K_{ow} = 9328** (TGAI?) **K_{ow} = 1.38×10^{5}** [Protocol 101/87] (PAI)
63-12. pH	**6.8-7.2** [CIPAC I, (1970): MT 75] (TGAI)
63-13. Stability	**stable under normal conditions for two years but susceptible to photodecomposition by sunlight and UV.**
63-14. Oxidizing/ reducing action	none submitted
63-15. Flammability	**N/A; product is a solid**
63-16. Explodability	none submitted
63-17. Storage Stability	none submitted
63-18. Viscosity	**N/A; product is a solid**
63-19. Miscibility	**N/A; product is a solid**
63-20. Corrosion Characteristics	none submitted

24

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TRIFLURALIN 98% TECHNICAL (AGAN CHEMICAL MANUFACTURERS, LTD.) 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 & Production Process	TGAI	R		X	40454701
61-3. Formation of Impurities	TGAI	R	X[3]		40454701
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR	X[4]		40454701
Physical and Chemical Characteristics					
63-2. Color	TGAI	R		X	40454701
63-3. Physical State	TGAI	R		X	40454701
63-4. Odor	TGAI	R		X	40454701
63-5. Melting Point	TGAI	R		X	40454701
63-6. Boiling Point	TGAI	R		X[5]	
63-7. Density/Specific Gravity	TGAI	R		X	40454701
63-8. Solubility	TGAI or PAI	R		X	40454701
63-9. Vapor pressure	TGAI or PAI	R		X	40454701
63-10. Dissociation Constant	TGAI or PAI	R	X[6]		
63-11. Octanol/Water Partition Coefficient	PAI	CR		X	40454701
63-12. pH	TGAI	CR		X	40454701
63-13. Stability	TGAI	R	X[7]		40454701
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[8]	

25

TABLE A. (Continued).

1. Data requirements pertain to the Agan Chemical Manufacturers, Ltd. 98% T (EPA Reg. No. 11603-13). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Trifluralin 98% Technical (Agan Chemical Manufacturers, Ltd.) 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. A discussion must be provided regarding the possible degradation of ingredients after production, post-production reactions between ingredients, and possible contamination from packaging materials.

4. Preliminary analysis for nitrosamines must be conducted on six samples from one representative batch of the product collected immediately after production (two samples), three months after production (two samples), and six months after production (two samples).

5. Data on boiling point are not required because the technical chemical is a solid at room temperature.

6. Data on dissociation constant are required if the PAI is an acid or a base.

7. Data re required regarding the methods and storage conditions used.

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

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE TRIFLURALIN 98% TECHNICAL (AGAN CHEMICAL MANUFACTURERS, LTD.) MANUFACTURING-USE PRODUCT.[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	40454701
61-2. Beginning Materials & Production/Formulation Process	MP	R		X	40454701
61-3. Formation of Impurities	MP	R	X[3]		40454701
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	CR	X[4]		40454701
62-2. Certified Limits	MP	R	X[5]		40454701
62-3. Enforcement Method	MP	R	X[6]		40454701
Physical and Chemical Characteristics					
63-2. Color	MP	R		X	40454701
63-3. Physical State	MP	R		X	40454701
63-4. Odor	MP	R		X	40454701
63-7. Density/Specific Gravity	MP	R		X	40454701
63-12. pH	MP	CR		X	40454701
62-14. Oxidizing/Reducing Action	MP	CR	X[7]		
62-15. Flammability	MP	CR		X[8]	
63-16. Explodability	MP	R	X[9]		
63-17. Storage Stability	MP	R	X		
63-18. Viscosity	MP	CR		X[8]	
63-19. Miscibility	MP	CR		X[8]	
63-20. Corrosion Characteristics	MP	R	X		

(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.)
Other Requirements:					
64-1. Submittal of Samples	MP	CR		X[10]	

1. Data requirements pertain to the Agan Chemical Manufacturers, Ltd. 98% T (EPA Reg. No. 11603-13). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Trifluralin 98% Technical (Agan Chemical Manufacturers, Ltd.) Technical Grade of the Active Ingredient."

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

3. A discussion must be provided regarding the possible degradation of ingredients after production, post-production reactions between ingredients, and possible contamination from packaging materials.

4. Preliminary analysis for nitrosamines must be conducted on six samples from one representative batch of the product collected immediately after production (two samples), three months after production (two samples), and six months after production (two samples).

5. A new upper certified limit is required for one impurity because the nominal concentration exceeds the reported upper limit.

6. Complete validation data are required for analytical methods used to determine the active ingredient, impurities, and nitrosamines.

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

8. Data are not required because the product is a solid at room temperature.

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

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

TRIFLURALIN (DOWELANCO; DEB NO. 7175)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 1 Page(s)
Appendix B: 3 Page(s)

Confidential Appendices to the Scientific Review of a Registration Standard Follow-up Report for the Pesticide Trifluralin by the Dietary Exposure Branch [Confidential FIFRA Trade Secret/CBI].

Page_____ is not included in this copy.

Pages 30 through 33 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

✓ Identity of product impurities.

✓ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

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

_____ The document is not responsive to the request.

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

TRIFLURALIN (AGAN; DEB No. 7177)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

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

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

34

Page_____ is not included in this copy.

Pages 35 through 40 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

✓ Identity of product impurities.

✓ Description of the product manufacturing process.

✓ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

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

_____ The document is not responsive to the request.

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