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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

OCT 29 1991

MEMORANDUM

SUBJECT: Trifluralin Product and Residue Chemistry Reregistration Standard Updates (CBRS's # 8100 and 7205; Barcode No.'s D157287 and D159654.).

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

Edward Zager

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

and

W. Burnam, Acting Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

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

Revised data requirement tables are included.

If you need additional input please advise.

Attachment 1: Trifluralin Product Chemistry Reregistration Standard Update.

Attachment 2: Trifluralin Residue Chemistry Reregistration Standard Update.

Attachment 3: Confidential Appendices A, B and C of the Trifluralin Product Chemistry Update

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

cc: Without Attachments: Circ. and RF

ATTACHMENT 1

TRIFLURALIN
(Chemical Code 036101)

TASK 3

Reregistration Standard Update

Product Chemistry

May 17, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

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4

TRIFLURALIN

(Chemical Code 036101)

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

INTRODUCTION

A Product Search Listing conducted on 12/05/90 identified seven manufacturing-use products of trifluralin, the 95% T (EPA Reg. No. 62719-99), 44.5% FI (Treflan® Emulsifiable Concentrate, EPA Reg. No. 62719-101), 20% FI (Treflan® Milled Concentrate, EPA Reg. No. 62719-133), and 50.8% FI (Treflan® 5, EPA Reg. No. 62719-172), all four registered by DowElanco; the 98% T (EPA Reg. No. 11603-13) registered by Agan Chemical Manufacturers, Ltd.; the 96% T (EPA Reg. No. 33660-3) registered by Industria Prodotti Chimici, S.P.A. and represented by Pazianos Associates; and the 96% T (EPA Reg. No. 19713-226) registered by Drexel Chemical Company.

The Trifluralin Guidance Document (4/87) requires additional generic and product-specific chemistry data for the technical product. In early 1990, Elanco merged with Dow Chemical to become DowElanco. Soon after, the Agency changed the EPA Reg. Nos. for the 95% T (1471-70), 44.5% FI (1471-72), 20% FI (1471-145), and 50.8% FI (1471-120) to its present registration numbers. DowElanco is using the data submitted (1987; MRID 40453301, 40453302, 40453303, 40453401, 40453402, 40453403, 40453404, and 40674703 [95% T], 40452701, 40452702, 40454102 [44.5% FI], 40453701, 40453702 [20% FI], 40453501, 40453502 [50.8% FI]; 1988; MRID 40674701, 40674702, 40674703 and 40674704 [95% T], 40674201, 40674203, [44.5% FI], 40675001, 40675002 [20% FI], 40673901, 40674602 [50.8% FI]; 1989; MRID 41241301 [95% T], 41251801 [50.8% FI]; 1990; MRID 41792901 [95% T]) by Elanco in support of the reregistration of DowElanco trifluralin technical and formulation intermediates. The following MRIDs 40453302, 40453303, 40453402, 40453403 and 40453404 for the 95% T were reviewed by the Agency (R. Perfetti, 3/5/91, CBRS No. 7175). The Agency concluded that data and information regarding product identity and disclosure of ingredients, the discussion of formation of impurities, preliminary analysis, certification of limits, enforcement analytical methods and physical and chemical characteristics (melting point, dissociation constant, octanol/water partition coefficient, stability, storage stability, and corrosion characteristics) remain outstanding. The bulk of the MRID data submitted by DowElanco are reviewed here for adequacy in fulfilling the requirements of the 95% T, 44.5% FI, 20% FI and 50.8% FI.

Agan Chemical Manufacturers, Ltd. submitted data (1987; MRID 40454701; 1988; MRID 40692701) in support of the reregistration of the 98% T (EPA Reg. No. 11603-13). MRID 40454701 was reviewed by the Agency (R. Perfetti, 3/5/91, CBRS No. 7177). The Agency concluded that the discussion on the formation of impurities, preliminary analysis for

nitrosamines, certification of limits, validation data for enforcement analytical methods, physical and chemical characteristics (dissociation constant, explodability, storage stability and corrosion characteristics) remain outstanding. MRID 40692701 data are reviewed here for adequacy in fulfilling the requirements of the 98% T.

Industria Prodotti Chimici, S.P.A. which is represented by Pazzianos Associates, submitted data (1987; MRID 40446902; 1988; MRIDs 40743901, 40743902 and 40834701) in support of the reregistration of the 96% T (EPA Reg. No. 33660-3). MRID 40446902 was reviewed by the Agency (R. Perfetti, 3/5/91, CBRS No. 7176). The Agency concluded that the product identity and composition (Guideline Ref. Nos. 61-1, -2, -3), analysis and certification of product ingredients (guideline Ref. Nos. 62-1, -2, -3) and storage stability (Guideline Ref. No. 63-17) remain outstanding. The data from MRIDs 40734901, 40743902, and 40834701 are reviewed here for adequacy in fulfilling the requirements for the 96% T.

Drexel Chemical Company has not submitted any data to support the reregistration of their 96% T (EPA Reg. No. 19713-226).

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 Requirements". These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of Trifluralin.

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

SUMMARY

The following Product Chemistry data are required for the DowElanco products:

95% T (EPA Reg. No. 62719-99)

- current information pertaining to all Guideline Reference 61 and 62 series product chemistry requirements.

6

44.5% FI (EPA Reg. No. 62719-101) and 20% FI (EPA Reg. No. 62719-133)

- o technical specifications of the inerts and solvents used and duration of the manufacturing process, post-production contamination, and discussion of the two methods referred to in the preliminary analysis, nominal concentration, certified limits, enforcement analytical methods and data for the impurities resulting from the technical product.

50.8% FI (EPA Reg. No. 62719-172)

- o technical specifications of the starting materials and detailed description of the manufacturing process used, discussion of the formation of impurities, preliminary analysis, nominal concentration, certified limits, enforcement analytical methods and data for the impurities resulting from the technical product.

The following Product Chemistry data are required for the Agan Chemical 98% T (EPA Reg. No. 11603-13):

- o discussion on post-production contamination, preliminary analysis of N-nitrosamines at initial production, three months and six months after production, certified limits, validation data for the analytical methods used to determine the active ingredient and impurities, physical and chemical properties.

The following Product Chemistry data are required for the Industria Prodotti Chimici 96% T (EPA Reg. No. 33660-3):

- o nominal concentration and CAS registry no. of the active ingredient, nominal concentration of the impurities present at ≥ 0.1%, relative amounts of starting materials, technical specifications and sources of some of the starting materials, duration of the manufacturing process, and description of physical conditions (temperature, pressure) and detailed description of the equipment used, discussion of post-production contamination, name and description of the analytical method used [redacted] during preliminary analysis, validation data for the analytical methods used to determine the active ingredient and impurities.

All Product Chemistry data are required for the Drexel 96% T (EPA Reg. No. 19713-226).

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

7

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

The Trifluralin Guidance Document (4/87) requires additional product-specific data concerning product composition. In response, DowElanco submitted data (1987; MRIDs 40452701, 40453301 and 40453701; 1989; MRIDs 41241301 and 41251801) to support the reregistration of the 95% T; 44.5% FI; 20% FI; and 50.8% FI; Agan Chemical Manufacturers, Ltd. submitted data (1987; MRID 40454701) for the 98% T; and Industria Prodotti Chimici submitted data (1988; MRID 40743902) for the 96% T.

DowElanco provided Confidential Statement of Formulas (1987; MRID 40453301; 1989; MRID 41241301) for the technical trifluralin. DowElanco's more recent data (1989; MRID 41241301) are presented in Confidential Appendix A. These data do not fully satisfy the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) regarding product identity and composition for the 95% T (EPA Reg. No. 62719-99) because the data do not cover the most recent manufacturing process. Additional data are required.

DowElanco provided a Confidential Statement of Formula for each of the 44.5% FI (EPA Reg. No. 62719-101), and 20% FI (EPA Reg. No. 62719-133), which are presented in Confidential Appendix A. Nominal concentrations for the impurities resulting from the technical product must be provided and included on the Confidential Statement of Formulas of the 44.5% and 20% FIs. Additional data are required.

DowElanco submitted an undated alternate Confidential Statement of Formula (1989; MRID 41251801) for the 50.8% FI (EPA Reg. No. 62719-172) which is presented in Confidential Appendix A. Nominal concentrations for impurities resulting from the technical product must be provided and included on the Confidential Statement of Formula for the 50.8% FI. Additional data are required.

Agan Chemical Manufacturers, Ltd. submitted data (1987; MRID 40454701) in support of the reregistration of the 98% T (EPA Reg. No. 11603-13). The Agency (R. Perfetti, 3/5/91, CBRS No. 7177) reviewed these data and concluded that the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) regarding product composition are fully met for the Agan 98% T. No additional data are required.

Industria Prodotti Chimici, S.P.A. submitted data (1988; MRID 40743902) in support of the reregistration of the 96% T (EPA Reg. No. 33660-3). The data do not fully satisfy the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) because the nominal concentration and CAS Registry No. of the active ingredient; and nominal concentration of the impurities that are present at $\geq 0.1\%$ by weight were not provided. Previously submitted data and any additional information must be reported on EPA Form 8570-4 (Rev. 2-85).

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Drexel Chemical Company did not submit any data to support the reregistration of its trifluralin 96% T (EPA Reg. No. 19713-226). All data pertaining to this topic are required for the Drexel product.

61-2. Starting Materials and Manufacturing Process

The Trifluralin Guidance Document (4/87) requires additional generic and product-specific data concerning the starting materials used and the manufacturing process. DowElanco submitted information (1987; MRID 40453302) in support of the reregistration of 95% T (EPA Reg. No. 62719-99). The Agency (R. Perfetti, 3/5/91, CBRS No. 7177) reviewed the data and concluded that the requirements of 40 CFR §158.162 (Guideline Ref. No. 61-2) are fully satisfied. However, information (K.W. Dockter, 3/5/90, CBRS No. 6186) received by EPA indicate that there has been a change in the manufacturing process. [redacted] Based on this, updated information on starting materials and manufacturing process must be provided. Additional information is required for the DowElanco 95% T.

DowElanco submitted information (1987; MRID 40452701) for the 44.5% FI (EPA Reg. No. 62719-101) which is presented in Confidential Appendix A. The requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) are not fully met because the technical specifications of the inerts and solvents, duration of the manufacturing process, and detailed description of the equipment and packaging materials used were not provided. Additional information is required for the 44.5% FI.

DowElanco submitted information (1987; MRID 40453701) for the 20% FI (EPA Reg. No. 62719-133), which is presented in Confidential Appendix A. The requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) are not fully met because the technical specifications of the inerts, duration of the manufacturing process, and description of the packaging materials used were not provided. Additional information is required for the 20% FI.

DowElanco provided (1989; MRID 41251801) only the name, source and amounts of the starting materials for the 50.8% FI (EPA Reg. No. 62719-172). The information provided do not fully satisfy the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) because technical specifications of the starting materials and a detailed description of the manufacturing process were not provided. Additional information is required for the 50.8% FI.

Agan Chemical Manufacturers, Ltd. submitted information (1987; MRID 40454701) to support the reregistration of the 98% T (EPA Reg. No. 11603-13). The Agency (R. Perfetti, 3/5/91, CBRS No. 7177) reviewed the submission and concluded that the information provided fully satisfies the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2).

Industria Prodotti Chimici submitted information (1988; MRID 40743901) to support the reregistration of the 96% T (EPA Reg. No. 33660-3). The submission does not satisfy the

requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) regarding the starting materials used and manufacturing process because the relative amounts of the starting materials, technical specifications and source of some of the starting materials, duration of the manufacturing process, description of physical conditions (temperature, pressure), and detailed description of the equipment used were not provided. Additional information is required.

All information pertaining to this topic is required for the Drexel trifluralin 96% T (EPA Reg. No. 19713-226).

61-3. Discussion of the Formation of Impurities

The Trifluralin Guidance Document (4/87) requires additional data regarding the formation of impurities. In response, DowElanco submitted information (1987; MRID 40453302) for the reregistration of the 95% T (EPA Reg. No. 62719-99). The Agency (R. Perfetti, 3/5/91, CBRS No. 7175) reviewed this submission and concluded that requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) are not fully met because possible degradation of ingredients and other post-production contamination were not discussed. DowElanco submitted additional data (1989; MRID 41241301) which indicate the presence of an impurity [redacted]. Additional information is required.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

DowElanco claimed (1987; MRIDs 40452701, 40453701) that there are no additional impurities formed in the preparation of 44.5% FI and 20% FI. Nitrosamine levels in these two formulation intermediates are well below the specified limits for both products. The information provided for the technical trifluralin does not fully satisfy the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3). Additional information is required for the 44.5% (EPA Reg. No. 62719-101) and the 20% FI (EPA Reg. No. 62719-133).

DowElanco did not provide discussion of the formation of impurities for the 50.8% FI (EPA Reg. No. 62719-172). Additional information is required.

Agan Chemical Manufacturers, Ltd. submitted information (1987; MRID 40454701) for the reregistration of the 98% T (EPA Reg. No. 11603-13). The Agency (R. Perfetti, 3/5/91, CBRS No. 7177) reviewed this submission and concluded that the discussion regarding the formation of impurities does not satisfy the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) because a post-production contamination discussion was not provided. Additional data are required.

Industria Prodotti Chimici, S.P.A. submitted data (1988; MRID 40743901) in support of the reregistration of 96% T (EPA Reg. No. 33660-3). The information provided is presented in the Confidential Appendix C. The information provided does not fully satisfy the

requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) because post-production contamination was not discussed. Additional data are required.

Drexel Chemical Company did not submit any information for the reregistration of its trifluralin 96% T (EPA Reg. No. 19713-226). All information pertaining to this topic is required for the Drexel product.

62-1. Preliminary Analysis

The Trifluralin Guidance Document (4/87) specifies that five or more recent samples of the technical product must be analyzed for the amount of the active ingredient, nitrosamines, and other impurities. DowElanco submitted data (1988; MRIDs 40674702 and 40674703) from the analysis of five batches of the 95% T (EPA Reg. No. 62719-99). [redacted] All data are presented in Confidential Appendix A. These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis because the registrant failed to provide data for two impurities that were listed on the Confidential Statement of Formula. It is not clear whether or not any attempt was made by the registrant to determine and quantify these two impurities. An additional impurity, which is not listed in the Confidential Statement of Formula, was detected at an average level of [redacted] by weight. The registrant failed to present data for the moisture content, [redacted] Finally, the data submitted are not pertinent to the most recent manufacturing process. Additional data are required.

DowElanco provided data (1988; MRID 40674201) for the 44.5% FI (EPA Reg. No. 62719-101). Five lots of technical trifluralin were assayed using Analytical Method AM-AA-CA-JO31-AB-755. The average was calculated and used for the potency of the technical. Five laboratory batches of Treflan® Emulsifiable Concentrate (44.5% FI) were produced according to the Confidential Statement of Formula of 44.5% FI, and assayed using Method AM-AA-CA-JO32-AB-755. Three lots of Treflan® Emulsifiable Concentrate were analyzed for total N- nitrosamine over a six month period according to Analytical Method BSR8801. The changes in nitrosamine levels upon storage were below the 0.45 ppm specified for this product. These data are presented in Confidential Appendix A. The information provided do not satisfy the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis because discussion of the two analytical methods AM-AA-CA-JO31-AB-755 and AM-AA-CA-JO32-AB-755 were not provided. Additional preliminary analysis is

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

required on five production batches of the manufacturing use products. The use of laboratory simulated samples is not acceptable. Additional data are required.

DowElanco provided data (1988; MRID 40675001) for the 20% FI (EPA Reg. No.62719-133). Five lots of technical trifluralin were assayed using Analytical Method AM-AA-CA-JO31-AB-755. The average was calculated and used for the potency of the technical. Five laboratory batches of Treflan® Milled Concentrate (20% FI) were produced according to the Confidential Statement of Formula of 20% FI, and assayed using Method AM-AA-CA-J371-AA-755. Two lots of Treflan® Milled Concentrate were analyzed for total N-nitrosamine over a twelve month period according to Analytical Method BSR8818. The changes in nitrosamine levels upon storage were below the 0.20 ppm specified for this product. These data are presented in Confidential Appendix A. The information provided do not satisfy the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis because discussion of the two analytical methods AM-AA-CA-JO31-AB-755 and AM-AA-CA-J371-AA-755 were not provided. Additional data are required.

DowElanco did not submit any preliminary analysis data for the 50.8% FI (Treflan® 5, EPA Reg. No. 62719-172). All data pertaining to this topic are required for this product.

Agan Chemical Manufacturers, Ltd. submitted data (1987; MRID 40454701) in support of the 98% T (EPA Reg. No. 11603-13). This submission was reviewed by the Agency (R. Perfetti, 3/5/91, CBRS No. 7177). It was determined that the data provided do not satisfy the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) because preliminary analysis for nitrosamines at three stages were not carried out. Additional data are required.

Industria Prodotti Chimici, S.P.A. submitted data (1988; MRID 40743902) for the reregistration of the 96% T (EPA Reg. No. 33660-3). Duplicate sets of seven batches were analyzed by gas liquid chromatography using I.Pi.Ci. analytical method AN/134/85 for the active ingredient in technical trifluralin. The manufacturing impurities were detected and quantified using I.Pi.Ci. analytical method AN/338/85. N-nitrosamines were quantified by GC/MS using I.Pi.Ci. analytical method AN/150/88 and by GC/TEA using I.Pi.Ci. analytical method AN/361/88. [redacted] was analyzed but the registrant failed to provide and discuss the method used. Chromatograms and chromatographic conditions were provided. All data are presented in Confidential Appendix C. It is not clear if the registrant carried out duplicate preliminary analysis of seven batches for the impurities as it did for the active ingredient. The data provided do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis. In addition the registrant did not discuss the method used to [redacted] the technical trifluralin. Additional data are required for the 96% T (EPA Reg. No. 33660-3).

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

Drexel Chemical Company did not provide preliminary analysis data for its trifluralin 96% T (EPA Reg. No. 19713-226). All data pertaining to this topic are required for this product.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

12

62-2. Certified Limits

The Trifluralin Guidance Document (4/87) requires certified limits for trifluralin, nitrosamines, and other impurities that are present at ≥ 0.1% by weight. In response, DowElanco submitted data (1987; MRID 40453301; 1989; MRID 41241301) in support of the reregistration of the technical trifluralin. The data are presented in Confidential Appendix A. The upper and lower limits for the active ingredient, trifluralin were established from the mean of the five assays, then adding and subtracting two standard deviations and rounding off to the nearest whole percentages. The upper limits for the impurities, except N-total nitrosamines, were established in a similar manner. The limits for the nitrosamines were established by the EPA in a PD 4 issued in July, 1982 (47FR33777). The data do not fully satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for 95% T (EPA Reg. No. 62719-99) because an upper certified limit was not provided by the registrant for the impurity detected at an average level of [redacted] by weight. This impurity is not listed on the Confidential Statement of Formula. Based upon the modified manufacturing process, the supplied CSFs do not account for all of the ingredients and significant impurities. Additional data are required.

DowElanco submitted data (1988; MRID 40674201) to support its reregistration of the 44.5% FI (EPA Reg. No. 62719-101) which are presented in Confidential Appendix A. The limits of technical trifluralin were determined using the precision of the analytical method AM-AA-CA-JO32-AB-755 for an emulsifiable concentrate and applying this figure to the range of the analytical results obtained from various studies. [redacted] Using the range from the preliminary analysis and applying the standard deviation from the analytical method, the range representing the certified limits of trifluralin was obtained. Certified limits for the impurities resulting from the technical product were not provided. Additional data are required to fully satisfy the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) regarding certified limits.

DowElanco submitted data (1988; MRID 40675001) to support the reregistration of the 20% FI (EPA Reg. No. 62719-133). The limits of technical trifluralin were determined by using the precision of the analytical method BSR8818 for Treflan® Milled Concentrate and applying this figure to the range of the analytical results obtained from [redacted] lots of 1986 production material. [redacted] Using the range from the preliminary analysis of the [redacted] lots [redacted] and applying the standard deviation from the analytical method, the trifluralin range representing the certified limits were set. Certified limits for the impurities resulting from the technical trifluralin were not provided. Additional data are required to fully satisfy the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) regarding certified limits.

DowElanco submitted an alternate Confidential Statement of Formula (1989; MRID 41251801) for the reregistration of the 50.8% FI (EPA Reg. No. 62719-172) which is presented in Confidential Appendix A. The information provided does not fully satisfy the

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED
QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

requirements of 40 CFR 158.175 (Guideline Ref. No. 62-2) regarding certified limits because the registrant failed to provide upper limits for the impurities resulting from the technical product. Additional information is required for the 50.8% FI.

Agan Chemical Manufacturers, Ltd. submitted data (1987; MRID 40454701) to support the reregistration of the 98% T (EPA Reg. No. 11603-13) which were reviewed by the Agency (R. Perfetti, 3/5/91, CBRS No. 7177). The data provided do not satisfy the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) because the upper certified limit for one impurity is exceeded by its nominal concentration. Additional data are required. Furthermore, the registrant must submit these certifications, along with nominal concentrations, on EPA Form 8570-4 (Rev. 2-85).

Industria Prodotti Chimici, S.P.A., submitted data (1988; MRID 40743902) to support the reregistration of 96% T (EPA Reg. No. 3360-3) which are presented in Confidential Appendix C. These data fully satisfy the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) regarding certified limits for the I.Pi.Ci. 96% T. However, these data should be resubmitted on EPA Form 8570-4 (Rev. 2-85).

Drexel Chemical Company did not submit any data to support the reregistration of its trifluralin 96% T (EPA Reg. No. 19713-226). All data pertaining to this topic are required for this product.

62-3. Enforcement Analytical Methods

The Trifluralin Guidance Document (4/87) specified that validated analytical methods for the enforcement of certified limits be submitted. DowElanco provided enforcement analytical methods (1988; MRID 40674704) for the technical trifluralin. Infrared and GLC methods were used for trifluralin identification. General Procedure 7013-1.5 or 7013 was used for total nitrosamine assay. Linearity of the trifluralin (0.9999 coefficient of determination) was demonstrated by assaying seven solutions ranging in concentrations from 0.24 mg/ml to 4.2 mg/ml. Precision was measured by assaying twelve samples of trifluralin on one day. The percent relative standard deviation was found to be 0.47. For the stability of assay solution, the twelve precision samples were reassayed after standing for 24 h. The ratio of aged/fresh solutions was found to be 99.5%. This demonstrated the stability of the analyte in its measurement solution for at least 24 h. A sample chromatogram is provided. The nitrosamine assay consisted of assaying five samples of trifluralin technical, which had been fortified with dipropylnitrosamine at doses ranging from 0.2 ppm to 1.4 ppm. The coefficient of determination was 0.9984. The assay procedure utilized the silica gel solid-phase extraction column and thermal energy analyzer. The five fortified samples gave a mean recovery equal to 100.1% and a percent relative standard deviation equal to 9.52. A sample chromatogram was also provided. There were no validation data presented for the capillary gas chromatograph technique used to determine the volatile impurities in technical trifluralin. Additional data are required for the 95% T (EPA Reg. No. 62719-99) to satisfy

the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3) regarding enforcement analytical methods.

DowElanco (1988; MRID 40674102) submitted enforcement analytical methods for the 44.5% FI (EPA Reg. No. 62719-101). The trifluralin was assayed using a suitable gas chromatograph equipped with a flame ionization detector. Linearity of the trifluralin was demonstrated by assaying seven solutions of Treflan® Emulsifiable Concentrate (44.5% FI) ranging in concentration from 0.50 mg/ml to 8.0 mg/ml. The coefficient of determination was 0.9999. Precision was evaluated by assaying twelve samples prepared on one day. The percent relative standard deviation was found to be 0.72. The twelve precision samples were reassayed after standing for 24 h. The ratio of aged/fresh solutions was found to be 1.003. This demonstrated the stability of the analyte in its measurement solution for at least 24 h. Day to day precision was evaluated by assaying six samples and one standard prepared on each of two separate days. The percent relative standard deviation was 0.67. This demonstrated that day-to-day precision was not significantly different from within day precision. Accuracy was evaluated by assaying five samples of Treflan® Emulsifiable Concentrate which had been fortified with standard trifluralin on each of two days. Recovery was 99% for the added trifluralin.

A nitrosamine assay was carried out using General Procedure 7013-.15. Linearity was demonstrated by assaying five samples of Treflan® Emulsifiable Concentrate (44.5% FI) which had been fortified with dipropylnitrosamine at doses ranging from 0.1 to 1.6 ppm. The coefficient of determination was 0.9957. The percent relative standard deviation was 5.13. Recovery was 93.5% for the added dipropylnitrosamine.

Chromatograms and chromatographic conditions were submitted for the above methods. However, validation data for the analytical method used to determine the impurities resulting from the technical product were not provided. The carrier gas was not specified. The data presented in Confidential Appendix A do not fully satisfy the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3) regarding enforcement analytical methods. Additional data are required for the 44.5% FI (EPA Reg. No. 62719-101).

DowElanco submitted (1988; MRID 40675002) enforcement analytical methods for the 20% FI (EPA Reg. No. 62719-133). Trifluralin assay was carried out using Hewlett-Packard 5880 GC (or equivalent) equipped with a flame ionization detector. Linearity of trifluralin was demonstrated by assaying five solutions of trifluralin with concentrations ranging from 0.5 to 1.5 mg/ml. The coefficient of determination was 0.9999. Precision was measured by assaying six samples of Treflan® Milled Concentrate (20% FI) on each of two days. The percent relative standard deviation was 1.76. Accuracy was evaluated by assaying five samples of Treflan® Milled Concentrate which had been fortified with trifluralin on each of two days. Recovery was 94.9% for the added trifluralin.

Nitrosamine assay was carried out using General Procedure 7013-.15. Linearity of the nitrosamine analysis was demonstrated by assaying five samples of Treflan® Milled

Concentrate (20% FI) which had been fortified with dipropylnitrosamine at doses ranging from 0.06 ppm to 0.72 ppm. The coefficient of determination was 0.9792. The percent relative standard deviation was 7.44. Recovery was 90.8% for the added dipropylnitrosamine.

Chromatograms and chromatographic conditions were provided. However, validation data were not provided for the analytical methods used to determine the impurities resulting from the technical product. The data presented in Confidential Appendix E do not fully satisfy the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3). Additional data are required for the 20% FI (EPA Reg. No. 62719-133).

DowElanco submitted enforcement analytical methods (1988; MRID 40674602) for the 50.8% FI (EPA Reg. No. 62719-172). Trifluralin was assayed using a Hewlett-Packard 5880 gas chromatograph (or equivalent instrument) equipped with a flame ionization detector. Linearity of trifluralin was demonstrated by assaying seven trifluralin solutions with concentrations ranging from 0.12 to 2.11 mg/ml. The coefficient of determination was 0.9999. Precision was evaluated by assaying six samples of Treflan® 5G (50.8% FI) on each of two days. The percent relative standard deviation was 2.38. Accuracy was evaluated by assaying five samples of Treflan® 5G which had been fortified with standard trifluralin on each of two days. The percent recovery was 104 for the added trifluralin.

A total nitrosamine assay was carried out using a TEA equipped with a gas chromatograph and an HP 388 computing integrator. Linearity of the nitrosamines was demonstrated by assaying five samples of Treflan® 5G (50.8% FI) which had been fortified with dipropylnitrosamine at doses ranging from 0.012 to 0.18 ppm. The coefficient of determination was 0.9859. The percent relative standard deviation was 7.61. The percent recovery was 106 for the added dipropylnitrosamine.

Chromatograms and chromatographic conditions were provided. However, validation data for the analytical method used to determine the impurities resulting from the technical product were not provided. Furthermore, the carrier gas and its flow rate were not specified. The data presented in Confidential Appendix A do not fully satisfy the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3) regarding enforcement analytical methods. Additional data are required for the 50.8% FI (EPA Reg. No. 62719-172).

Agan Chemical Manufacturers, Ltd. submitted data (1987; MRID 40454701; 1988; MRID 40692701). MRID 40454701 data were reviewed by the Agency (R. Perfetti, 3/5/91, CBRS No. 7177) and found to be inadequate.

The additional document (1988; MRID 40692701) contains validation data for N-nitrosamines from two lots of technical trifluralin. A gas chromatograph equipped with thermal energy analyzer was used to detect nitrosamine levels. The validation data submitted for nitrosamine analysis are satisfactory. There were no validation data provided in this submission (1988;

MRID 40692701) for the analytical methods used to determine the active ingredient and volatile impurities in the technical trifluralin. Additional data are required.

Industria Prodotti Chimici provided data (1988; MRID 40743902) on recovery factors for two nitrosamines. Recovery was carried out by GC/MS using analytical method AN/150/88. Chromatograms were provided. Retention times were listed for five other nitrosamines but it is not clear whether or not an attempt was made to determine their presence or absence. Validation data for the analytical methods used to determine the active ingredient and other impurities in the technical product were not provided. Additional data are required for the 96% T (EPA Reg. No. 33660-3).

Drexel Chemical Company did not submit any data for the reregistration of its trifluralin 96% T (EPA Reg. No. 19713-226). All data pertaining to this topic are required for this product.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Trifluralin Guidance Document (4/87) specifies generic and product-specific data requirements for technical trifluralin. In response, DowElanco submitted data (1987; MRIDs 40453302, 40453401, 40453402, 40453403, 40453404) for 95% T; (1987; MRID 40452702) for 44.5% FI; ((1987, MRID 40453702) for 20% FI, and (1987; MRID 40453502) for 50.8% FI; Agan submitted data (1987; MRID 40454701) for the 98% T; and Industria Prodotti Chimici submitted data (1987; MRID 40446902; and 1988; MRID 40834701) for the 96% T, pertaining to the physical and chemical characteristics of the technical trifluralin. A majority of this data has been previously reviewed by the Agency (R. Perfetti, 3/5/91, CBRS Nos. 7175, 7176 and 7177).

17

Table 1. Physical and Chemical Properties of DowElanco Technical Trifluralin (95% T), Treflan® Emulsifiable Concentrate (44.5% FI), Treflan® Milled Concentrate (20% FI), and Treflan® 5 Herbicide (50.8% FI); Agan Triflurex (98% T); and Industria Prodotti Technical Trifluralin (96% T).

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-2. Color	**yellow-orange** (95% T; TGAI; 62719-99; 40453401) **red-orange** (44.5% FI; 62719-101; 40452702) **light-yellow** (20% FI; 62719-133; 40453702) **red-orange** (50.8% FI; 62719-172; 40453502) **orange** 98% T; TGAI; 11603-13; 40454701) **orange-red** (96% T; TGAI; 33660-3; 40446902)
63-3. Physical State	**yellow-orange prisms** (95% T; TGAI; 62719-99; 40453401) **liquid** (44.5% FI; 62719-101; 40452702) **free flowing powder** (20% FI; 62719-133; 40453702) **liquid** (50.8% FI; 62719-172; 40453502) **crystalline solid** (98% T; TGAI; 11603-13; 40454701) **crystalline solid** (96% T; TGAI; 33660-3; 40446902)

(continued)

18

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-4. Odor	**aromatic solvent odor** (95% T; TGAI; 62719-99; 40453401) **aromatic odor** (44.5% FI; 62719-101; 40452702) **mild aromatic** (20% FI; 62719-133; 40453702) **aromatic odor** (50.8% FI; 62719-172; 40453502) **characteristics of organics** (98% T; TGAI; 11603-13; 40454701) **odorless** (96% T; TGAI; 33660-3; 40446902)
63-5. Melting Point	**47 °C** [OECD No. 102 Capillary method] (95% T; TGAI; 62719-99; 40453401) **42-48 °C** (98% T; TGAI; 11603-13; 40454701) **48.5-49.0 °C** (98% T; PAI; 11603-13; 40454701) **45-48 °C** [CIPAC MT 2] (96% T; TGAI; 33660-3; 40446902)
63-6. Boiling Point	**87 °C - weight loss to total volatilization** [Thermo-gravimetric analysis] **50 °C - Endotherm melt** **[Differential Thermal Analysis]** **275 °C - Decomposition** (95% TGAI; 62719-99; 40453401) **N/A - TGAI is solid** (98% T; TGAI; 11603-13; 40454701) **N/A - TGAI is solid** (96% T; TGAI; 33660-3; 40446902)

(continued)

19

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-7. Bulk Density	**0.60 g/cc (loose)** [Eli Lilly and Company General Lab. Procedure GP7011.] (95% T; TGAI; 62719-99; 40453401) **1.060 - 1.070 g/mL** [Method AM-AA-CA-F020-AA-650] (44.5% FI; 62719-101; 40452702) **38-43 lb/cu ft. packed** **20-25 lb/cu ft. loose** [Method AM-AA-CA-F020-AA-659] (20% FI; 62719-133; 40453702) **1.136-1.186 g/mL** [Method AM-AA-CA-F020-AA-659] (50.8% FI; 62719-172; 40453502) **1.30 g/cm^3** (98% T; TGAI; 11603-13; 40454701) **1.126 g/mL** [CIPAC MT 3.2.1] (96% T; PAI; 33660-3; 40446902)
63-8. Solubility	**water** **0.3 ppm [Coupled column liquid chromatographic technique]** **hexane** **5.0 - 6.7 g/100 mL** **methanol** **3.3 - 4.0 g/100 mL** **acetone, acetonitrile, chloroform, dichloromethane, ethyl acetate and toluene** **>100 g/mL[a]** [Procedure No. AM-AA-CA-J073-AA-755] (95% T; TGAI; 62719-99; 40453401 and 40453403)

(continued)

20

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)	
	water (25 °C)	**0.2 ppm at pH 5**
		0.2 ppm at pH 7
		0.3 ppm at pH 9
	acetone (20 °C)	**40 g/100 mL**
	dioxane (25 °C)	**83 g/100 mL**
	hexane (25 °C)	**>50 g/100 mL[a]**
	methanol (25 °C)	**2 g/100 mL**
	xylene (25 °C)	**81 g/100 mL**
	dimethylformamide (25 °C)	**82 g/100 mL**
	methyl cellosolve (25 °C)	**44 g/100 mL**
	[EPA Method GC-1500 8/82]	
	(98% T; PAI; 11603-13; 40454701)	
	20 °C	
	water	**10^{-4} g/100 mL**
	acetone	**32 g/100 mL**
	xylene	**48 g/100 mL**
	[OECD 105]	
	(96% T; TGAI; 33660-3; 40446902)	
63-9. Vapor pressure (25 °C)	**1.03 x 10^{-4} mm Hg**	
	[Gas chromatographic Head Space technique]	
	(95% T; PAI; 62719-99; 40453401 and 40453404)	
	4.85 x 10^{-5} mm Hg	
	(98% T; TGAI; 11603-13; 40454701)	
	9.13 x 10^{-5} mm Hg	
	[Protocol 121/87]	
	(98% T; PAI; 11603-13; 40454701)	
	1.27 x 10^{-4} mm Hg	
	[OECD Guidelines, Section 1, Number 4]	
	(96% T; PAI; 33660-3; 40446902)	

(continued)

21

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-10. Dissociation constant	**No titrable group was found in acidic, neutral or basic solutions by aqueous spectrophotometric titration or by potentiometric titration in 66% DMF between pH 3.5 and 13.5.** [OECD No. 112] (95% T; TGAI; 62719-99; 40453401)
	not submitted (40454701)
	does not dissociate [conductivity] (96% T; PAI; 33660-3; 40446902)
63-11. Octanol/water partition coefficient	**K_{ow} = 118,000** **Log K_{ow} = 5.07** [OECD No. 107] (95% T; PAI; 62719-99; 40453401)
	K_{ow} = 9328 (98% T; TGAI; 11603-13; 40454701) **K_{ow} = 1.38 x 10^5** [Protocol 101/87] (98% T; PAI; 11603-13; 40454701)
	p = 3.33 x 10^3 [OECD 112] (96% T; PAI; 33660-3; 40446902)

(continued)

72

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-12. pH	**6.4 (10% slurry in distilled water)** **5.6 (10% slurry in tap water)** [Procedure AM-AA-CA-F008-AA-659] (95% T; TGAI; 62719-99; 40453401) **between 4.5 and 8.0 (50% mixture in water)** [Method AM-AA-CA-F008-AA-659] (44.5% FI; 62719-101; 40452702) **between 4.0 and 5.4 (10% slurry in water)** [Method AM-AA-CA-F008-AA-659] (20% FI; 62719-133; 40453702) **between 4.2 and 6.5 (50% mixture in water)** [Method AM-AA-CA-F008-AA-659] (50.8% FI; 62719-172; 40453502) **6.8-7.2** [CIPAC I, (1970); MT75] (98% T; TGAI; 11603-13; 40454701) **6-7** [ASTM E 70-74] (96% T; TGAI; 33660-3; 40446902)
63-13. Stability	**stable up to 36 months at 25 °C** **stable up to 9 months at 37 °C** **stable up to 6 months at 52 °C** (95% T; TGAI; 62719-99; 40453401) **Stable under normal conditions for two years but susceptible to photo-decomposition by sunlight and UV.** (98% T; TGAI; 11603-13; 40454701) **Stable in acid and alkaline medium; decomposes when exposed to sunlight; slowly degrades at high temperatures.** [GC] (96% T; TGAI; 33660-3; 40446902)

(continued)

23

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-14. Oxidizing/reducing action	No gas evolution or temperature increase in ammonium dihydrogen phosphate, potassium permanganate and powdered zinc. [Method AM-AA-CA-F014-AA-659] (95% T; TGAI; 62719-99; 40453401) (44.5% FI; 62719-101; 40452702) (20% FI; 62719-133; 40453702) (50.8% FI; 62719-172; 40453502)
	none submitted (98% T; TGAI; 11603-13; 40454701)
	No temperature increase or product decomposition in water, CO_2, iron and zinc. [Federal Reg. 44, No. 53, p 16267] (96% T; TGAI; 33660-3; 40446902)
63-15. Flammability	between 108 °F and 114 °F (42.2 °C and 45.6 °C) [Method AM-AA-CA-F016-AB-659] (44.5% FI; 62719-101; 40452702) N/A - dry product (20% FI; 62719-133; 40453702) the closed cup flash point is 110 °F (43 °C) [Method AM-AA-CA-F016-AB-659] (50.8% FI; 62719-172; 40453502)
	N/A - product is a solid (98% T; TGAI; 11603-13; 40454701)
	N/A - product is a solid (96% T; TGAI; 33660-3; 40446902)

24

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-16. Explodability	**not impact sensitive** [Method AM-AA-CA-F006-AA-659] (95% T; TGAI; 62719-99; 40453401) **The product yielded an auto-ignition temperature of 554 °F (290 °C) and a lower explosion limit in air of 1.2±0.1 mol. percent at 100 °C.** [Method AM-AA-CA-F019-AA-659] (44.5% FI; 62719-101; 40453702) **not impact sensitive** (20% FI; 62719-133; 40453702) **The product yielded an auto-ignition temperature of 572 °F (300 °C) and a lower explosion limit in air of 1.55±0.1 mol percent at 90 °C.** (50.8% FI; 62719-172; 40453502) **none submitted** (98% T; TGAI; 11603-13; 40454701) **not sensitive to impact** [UN document ST/SG/AC.10/11, Test 3(a)(ii)] (96% T; TGAI; 33660-3; 40446902)

(continued)

25

Table 1. (continued)

Guidelines Reference No.of 40 CFR §158.190 Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-17. Storage stability	**The technical product stored in a lined fiber drum, and a carbon steel cylinder demonstrated good stability for 12 months at ambient laboratory conditions.** (95% T; TGAI; 62719-99; 41792901) **The product stored in gas treated high density polyethylene containers demonstrated good stability for 48 months at ambient temperatures.** (44.5% FI; 62719-101; 40452702) **The product stored in foil lined Kraft bags demonstrated good stability for 12 months at 37 °C and ambient temperatures.** (20% FI; 62719-133; 40453702) **The product stored in glass containers demonstrated good stability for three months at 25 °C, 37 °C and 52 °C. A study is in progress for product stored in one gallon steel drums coated with an ethoxy-phenolic lining to simulate trade package - results will be reported at a later date.** (50.8% FI; 62719-172; 40453502) **none submitted** (98% T; TGAI; 11603-13; 40454701) **The product stored in impermeable 250 kg iron drums demonstrated good stability for 12 months at room temperatures (-5 °C to +35 °C)** (96% T; TGAI; 33660-3; 40834701)

(continued)

26

ATTACHMENT 2

TRIFLURALIN

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 3

Table of Contents

TRIFLURALIN

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 3

INTRODUCTION

Trifluralin (α,α,α-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine) is a selective herbicide registered for the preemergence control of annual grasses and broadleaf weeds in asparagus, barley, carrots, cotton, flax, hops, legumes forage, beans (mung, castor, guar, lima, and snap), dry beans (navy, kidney, and pinto), peanuts, peppermint, rapeseed, safflower, spearmint, sugarcane, sunflower, wheat, celery, cole crops, greens (turnip, kale, collard, and mustard), okra, peas, peppers, potatoes, soybeans, and tomatoes. Trifluralin is registered for the postemergence control of annual grasses and broadleaf weeds in alfalfa, field corn, sorghum, cotton cucurbits, mint (peppermint and spearmint), potatoes, sugar beets, sugar cane, tomatoes, and onions. Trifluralin is also registered for application to the following: (i) new plantings of citrus (nectarines), fruit (apricot, and peach) and nut (walnut) trees and vineyards; (ii) non-bearing established plantings of citrus and pecans; (iii) bearing plantings of nuts (almonds, pecans, and walnuts), fruits (apricots, nectarines and peaches), and citrus (grapefruit, lemons, oranges, tangeloes, and tangerines); and (iv) post-plant applications on bearing or non-bearing established plantings of vineyards, nuts (almonds, pecans, and walnuts), fruits (apricots, peaches, nectarines, and plums), and citrus (grapefruits, lemons, oranges, tangeloes and tangerines). Trifluralin is registered for soil and foliar application using aerial or ground equipment. Residue tolerances for trifluralin are expressed in terms of the parent compound (40 CFR §180.207).

The Trifluralin Guidance Document dated April, 1987 required data regarding the nature of the residue in plants, poultry and ruminants, including the analysis of representative samples from metabolism studies using enforcement methods. Data pertaining to the storage intervals and conditions of storage of samples used to support all established tolerances for residues were also required. In addition, residue data were required for corn grain, sorghum grain, corn forage and fodder, alfalfa hay, flax straw, and peppermint and spearmint. Tolerance proposals and supporting residue data were required for sorghum hay, alfalfa forage, cotton forage, peanut vines and hay, sugarcane forage, wheat, and sunflower forage; and processing data were required for potatoes, sugar beets, soybeans, oranges, flax, cottonseed, peanuts, peppermint, spearmint, sugarcane, alfalfa, corn, and sunflower seeds.

In response to the Guidance Document, Elanco Products Company submitted studies pertaining to the nature of the terminal residues of trifluralin in corn (1989; MRID 41179001 and 41179002), which were reviewed by the Agency (E. T. Haeberer, CBRS No. 5644, October 6, 1989), and studies pertaining to the nature of the residues of trifluralin in ruminants and poultry (1989; MRIDs 41233101 and 41233102), which were reviewed by the

Agency (R.D. Schmitt, CBRS No. 5927, November 14, 1989). In response to the Agency letter of January 23, 1990, E. Tinsworth, Director, SRRD (see CBRS No. 5927), DowElanco submitted additional data on feeding levels of poultry and ruminants for previously submitted metabolism studies (MRIDs 41233101 and 41286101) that were reviewed by the Agency (E.T. Haeberer, CBRS No. 6568, April 16, 1990). In response to the review by E. T. Haeberer of October 6, 1989, CBRS No. 5644, DowElanco submitted supplemental information (1990; MRIDs 41396801 and 41396802) that have undergone Agency review (E. T. Haeberer, CBRS No. 6432, March 16, 1990). In addition, DowElanco has submitted data concerning the storage stability of trifluralin in plant matrices (1989; MRID 41335901; CBRS No. 7205), and the magnitude of the residue in sugarcane (1989; MRID 41306701), which are reviewed in this update for their adequacy in fulfilling outstanding data requirements.

Pertinent data that predate the Guidance Document but not discussed in the Chapter are reviewed here for their adequacy in fulfilling requirements for residue data on alfalfa (1984; MRID 00143667, and 1985; MRID 00155395).

SUMMARY

The following additional data are required:

- The storage intervals and conditions of the samples used to support all established tolerances for residues must be submitted. All residue data requested must be accompanied by data regarding storage length and conditions of storage of samples analyzed.

- Residue data are required for corn grain, sorghum grain, corn forage and fodder, alfalfa hay, flax straw, and peppermint and spearmint. Tolerance proposals and supporting residue data are required for sorghum hay, alfalfa forage, cotton forage, peanut vines and hay, sugarcane forage, wheat, and sunflower forage; and processing data are required for potatoes, sugar beets, soybeans, oranges, flax, cottonseed, peanuts, peppermint, spearmint, sugarcane, alfalfa, corn, and sunflower seeds.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The Trifluralin Guidance Document (April, 1987) requested additional data depicting the distribution and nature of residues of ring-labeled [^{14}C]trifluralin in mature, fresh and dry corn kernels, and in forage harvested at intervals following an over-the-top spray application, and the distribution and nature of residues in a mature leafy or Brassica leafy vegetable following a preplant soil application.

In response to the Guidance Document, Elanco Products Company submitted studies pertaining to the nature of the terminal residues of trifluralin in corn and mustard greens (1989; MRID 41179001 and 41179002) that were reviewed by the Agency (E. T. Haeberer, CBRS No. 5644, October 6, 1989). The reviewer concluded that the nature of the residue in plants remains inadequately defined for the following reasons: (i) no residues were conclusively identified in or on corn fodder; (ii) <50% of the ^{14}C-residues in corn forage were characterized; (iii) the radioactive residues released by hydrolysis of insoluble and aqueous fractions of corn forage were not identified; and (iv) over 60% of the total radioactive residues in mustard leaf tissues was not characterized.

In response to the review of October 6, 1989, DowElanco submitted supplemental information (1990; MRIDs 41396801 and 41396802), reviewed by E.T. Haeberer (CBRS No. 6432; March 16, 1990), who concluded that the nature of the residue in corn is adequately defined. Trifluralin is the predominant residue in forage. Very little if any residues translocate to grain or cob, and with time, residues on corn plants are converted from nonpolar to polar compounds and subsequently incorporated into insoluble forms including cell wall components. The nature of the residue in mustard leaves is adequately defined. The residue of concern is trifluralin. Although small amounts of trifluralin metabolites have been identified in mustard leaves treated at 2.6x, it is unlikely that they would result from treatment at 1x the maximum registered rate. No additional data are required.

References (used):

MRIDs: 41179001. 41179002. 41396801. 41396802.

Discussion of the data:

N/A. — ?? without

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The Trifluralin Guidance Document (April, 1987) requested data pertaining to the nature of the terminal residues of trifluralin in ruminants and poultry, including the analysis of representative samples from the metabolism studies using enforcement methods. In response, the registrant submitted studies pertaining to the nature of the residues of trifluralin in ruminants and poultry (1989; MRIDs 41233101 and 41233102) which were reviewed by the Agency (R.D. Schmitt, CBRS No. 5927, November 14, 1989). The reviewer concluded that the nature of the residue in animals is adequately understood; however, he specified that the registrant should report the weights of the hens and the dairy cow and the amount of feed consumed per day by the steers and hens.

In response to the Agency letter of January 23, 1990, E. Tinsworth, Director, SRRD (see CBRS No. 5927, DowElanco has submitted additional data on feeding levels of poultry and ruminants for previously submitted metabolism studies (MRIDs 41233101 and 41286101) which were reviewed by the Agency (E.T. Haeberer, CBRS No 6568, April 16, 1990). The CBRS reviewer concluded that the deficiencies concerning the ruminant and poultry metabolism studies are now resolved.

The qualitative nature of the residue in poultry and ruminants was found to be adequately understood by the reviewers. The residue of concern is trifluralin. No additional data are required.

References (used):

MRIDs: 41233100. 41233101. 41233102.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Conclusions:

The Trifluralin Residue Chemistry Chapter of July 3, 1985 indicated that adequate methods were available to determine trifluralin residues per se in or on plant commodities for data collection and enforcement purposes. The methods described included procedure nos. 5801000, and 5801210. Also included was a modification to these, procedure no. 5801616. These methods involve GC analysis with electron capture detection. Minor procedures, designed for particular crops and/or used only for a small part of data collection, included procedure no. 5801160, used for analysis of peanut meats and safflower oil and seed, procedure no. 5800600 used for analysis of tomatoes, procedure no. 5801577 used for analysis of mint oil, a nondesignated procedure of Monsanto Co. for the analysis of trifluralin oil seed crops which involved extraction with iso-octane and cleanup with alumina column. Also included were procedure no. MMS-R-274-1 (Shell Chemical Co.) used for data collection of soybeans and processed products of soybeans, a non-designated procedure of the Interregional Research Project No. 4 used for data collection in rape seed and straw, and procedure no. 5801110 which incorporates a TLC cleanup step to be used in the presence of interfering pesticides. Of these methods, the following are listed in PAM, Vol. II: Procedures 5801110, 5801210, and 5801577 of Eli Lilly and Co. (methods A, II, and B, respectively; Pesticide Reg. Section 180.207). Procedure no. 5801210 (PAM Vol. II, Sec. 180.207 Method II) was subjected to a Agency validation trial (see memorandum dated June 14, 1967, J. Wolff, cited in the Residue Chemistry Chapter). The Eli Lilly Method AM-

AA-CA-RO23-AA-755 was used for the generation of trifluralin residue data in soybeans only. This method is a modification to procedure no. 5801616 which is a modification of procedure no. 5801210 (PAM Vol. II, Sec. 180.207 Method II). Modifications included differing dilution solvents and GC columns.

The Residue Chemistry Chapter indicated that Elanco procedure no. 5801110 (PAM Vol. II, Sec. 180.207 Method A) is the preferred regulatory method when interfering pesticides are present in the crop sample. This method has since been validated as an enforcement method and is included in PAM II as Method III (F. D. Griffith, memo dated June 20, 1986).

In addition, the Residue Chemistry Chapter described an undesignated method for the GC analysis of trifluralin in bovine milk, urine, feces, and rumen contents. Samples are extracted, partitioned for cleanup and analyzed by GC using electron affinity detection.

The Eli Lilly Method AM-AA-CA-RO23-AA-755 was used for the generation of trifluralin residue data on sugarcane (1989; MRID 41306701) and alfalfa (1984; MRID 00143667 and 1985; MRID 00155395) that are discussed later in this update. Recoveries of trifluralin were 76-108% from samples fortified at 0.04 ppm. Recoveries were 72% and 80% for sugarcane fortified at 0.01 ppm and 0.05 ppm, respectively. Sugarcane processed commodities were fortified at 0.01 ppm, 0.05 ppm, and 0.1 ppm and the recoveries were 77-89% from bagasse, 85-96% from molasses, and 89-97% from sugar.

The Pestrack Data Base dated November 6, 1990 indicated that Trifluralin is completely (>80%) recovered using Multiresidue Protocols 211.1, 212.1 and 232.4.

At the present time, no tolerances exist for trifluralin residues in animal commodities. The poultry and ruminant metabolism studies indicate that residues of trifluralin should be regulated in meat, milk, poultry, and eggs. Thus, validated analytical methods for data collection and tolerance enforcement are required.

- Residue analytical methods suitable for data collection and tolerance enforcement must be submitted for determination of trifluralin in ruminant and poultry tissues, and eggs.

References (used):

N/A.

Discussion of the data:

N/A.

STORAGE STABILITY DATA

Conclusions:

The Trifluralin Guidance Document, dated April 1987, required additional data reflecting the stability of trifluralin residues of concern in stored samples. The requirement specifies that storage stability data must accompany all residue data submitted in response to the Guidance Document, except in cases where samples are stored at room temperature for up to 4 months or frozen for up to 10 months.

In response to this requirement, DowElanco submitted data (1989; MRID 41335901; CBRS No. 7205) pertaining to the storage stability of trifluralin residues in or on 24 crop matrices. These data are reviewed here for their adequacy in fulfilling outstanding residue chemistry data requirements.

The results indicate that residues of trifluralin are stable in wheat forage, wheat straw, cottonseed, and soybean oil stored for 554 days, corn grain stored for 192 days, garlic stored for 79 days, peas stored for 272 days, and carrots stored for 90 days at -15 °C. Residues were stable for 125, 62, and 60 days of frozen storage in or on grapes, sugarcane, and turnip greens, respectively, although residues declined 20-30 percent at 180, 124, and 119 days. Residues declined ca. 20-30 percent in potatoes stored for 188 days, green hops stored for 120 days, cabbage stored for >60 days, plums stored for 180 days, cantaloupes stored for 60 days, sunflower seeds stored for >60 days, dry beans stored for >30 days, and alfalfa hay stored for >60 days. Residues declined ca. 35 percent in peanut nutmeats after 120 days. Residues were not stable in or on flax seed or wheat grain, decreasing ca. 40-50 percent at the first analysis interval.

The registrant should be advised that, depending on the intervals and conditions of sample storage, corrections for residue decline during storage may be needed for residues in or on grapes, sugarcane, turnip greens, cabbage, cantaloupe, potatoes, plums, green hops, alfalfa hay, sunflower seeds, peanut nutmeats, peanut hulls, and dry beans. These data indicate that the Guidance Document conclusions regarding storage stability data may not be valid for all commodities; specifically, such data may be needed for commodities stored for 4 months at ambient temperature and 10 months at frozen temperatures. We recommend that in future residue tests with flax seed and wheat grain, samples be analyzed immediately after harvest, or frozen following harvest with simultaneous storage stability studies.

The following data are required:

- Storage data are required in support of all required and previously submitted residue studies, reflecting the actual storage conditions and intervals for samples used to generate the residue data.

References (used):

MRID: 41335901.

Discussion of the data:

Samples of crop matrices were chopped or ground and subsamples were placed in polyethylene bottles similar to those used for samples from residue field trials. Thirty subsamples of each matrix were fortified with trifluralin at levels equivalent to the established tolerances, and 45 additional subsamples served as controls. Perishable samples (wheat forage, potatoes, alfalfa hay, garlic, green peas, plums, cantaloupe, grapes, hops, sugarcane, turnip tops, cabbage, and carrots) were stored at -25 to -15 °C, and non-perishable commodities (cottonseed, flax seed, soybeans, soybean oil, wheat grain and straw, dry beans, field corn grain, peanut nutmeats and hulls, and sunflower seed) were stored at 20 to 25 °C for 7 days, refrigerated for 53 days at ca. 4 °C, then transferred to frozen storage at -25 to -15 °C for the duration of the tests.

The fortified commodity subsamples were analyzed at 15- or 30-day intervals for total storage times of 90-540 days. Controls were removed from storage, fortified, and analyzed concurrently with the test samples. Samples were analyzed using Eli Lilly method AM-AA-CA-RO23-AA-755, in which residues in all matrices except soybean oil were extracted with methanol, partitioned to methylene chloride following addition of sodium chloride to the extract, and dissolved in hexane after evaporation of the methylene chloride. Soybean oil was dissolved in hexane and cleaned up by partitioning with acetonitrile. The hexane extracts were cleaned up on Florisil and evaporated to dryness. The residues were dissolved in toluene and analyzed using GLC/electron capture (EC). The reported results were corrected for method recovery and, in the single case of garlic, apparent residues in control samples. The results are summarized in Table 1. Two samples of each commodity were analyzed at each interval. The reported results were corrected for recovery from samples fortified on the day of analysis.

Table 1. Recovery of trifluralin residues from fortified samples following storage.

Commodity	Fortification (ppm)	Interval (days)	Recovery (percent)
Wheat Forage	0.05	0	95, 97
		29	94, 97
		61	98, 101
		124	99, 100
		182	91, 96
		365	97, 102
		554	93, 94
Potatoes	0.05	0	84, 96
		31	79, 79
		58	84, 86
		135	91, 91
		188	76, 81
		365	85, 85
Garlic	0.05	0	106, 102
		30	95, 123
		58	82, 95
		79	82, 95
Green Peas	0.05	0	103, 101
		29	89, 91
		58	93, 84
		134	95, 98
		182	85, 85
		272	90, 88
Plums	0.05	0	99, 108
		32	88, 89
		60	81, 74
		139	76, 80
		181	63, 69
		271	75, 65
Cantaloupe	0.05	0	98, 98
		31	88, 87
		61	72, 80
		124	73, 83
		194	72, 82

(continued)

Table 1. (continued)

Commodity	Fortification (ppm)	Interval (days)	Recovery (percent)
Grapes	0.05	0	94, 93
		31	84, 89
		61	92, 91
		125	95, 94
		182	71, 85
Green Hops	0.05	0	102, 95
		31	83, 81
		60	77, 81
		122	75, 100
		178	73, 74
Sugarcane	0.05	0	99, 100
		29	92, 99
		62	99, 95
		124	72, 80
		182	85, 90
Turnip Greens	0.05	0	99, 102
		31	95, 89
		51	112, 116
		59	101, 98
		119	83, 76
		182	94, 88
Peanut Meats	0.05	0	99, 105
		30	81, 79
		61	72, 78
		120	66, 63
		180	77, 81
Cabbage	0.05	0	99, 97
		14	91, 93
		28	91, 92
		60	95, 99
		90	80, 84

(continued)

Table 1. (continued)

Commodity	Fortification (ppm)	Interval (days)	Recovery (percent)
Carrots	1.0	0	102, 100
		14	100, 96
		28	99, 98
		60	98, 96
		90	101, 100
Cottonseed	0.05	0	105, 106
		30	89, 88
		58	87, 88
		115	87, 84
		182	90, 86
		364	89, 89
		557	87, 85
Flax Seed	0.05	0	97, 102
		29	56, 51
		58	53, 53
		135	49, 49
		181	44, 49
		364	61, 61
		553	58, 55
Soybeans	0.05	0	105, 106
		30	71, 71
		58	72, 67
		115	67, 64
		182	62, 55
		364	61, 60
		555	72, 72
Soybean Oil	0.05	0	98, 98
		30	95, 104
		58	91, 93
		120	86, 87
		182	101, 101
		364	108, 95
		555	86, 98

(continued)

38

Table 1. (continued)

Commodity	Fortification (ppm)	Interval (days)	Recovery (percent)
Wheat Straw	0.05	0	101, 100
		29	96, 97
		61	94, 95
		119	85, 87
		182	91, 89
		365	97, 95
		553	90, 92
Wheat Grain	0.05	0	97, 108
		34	62, 57
		61	66, 72
		119	59, 60
		182	58, 57
		365	66, 71
Alfalfa Hay	0.02	0	98, 100
		30	80, 86
		59	80, 83
		123	74, 72
		182	78, 75
		273	81, 85
Dry Beans	0.05	0	97, 96
		30	96, 89
		57	71, 72
		121	72, 68
		191	88, 89
Corn Grain	0.05	0	106, 101
		30	99, 93
		65	86, 87
		121	82, 83
		192	91, 91
Peanut Hulls	0.1	0	99, 96
		31	75, 79
		60	83, 84
		122	60, 77
		178	108, 74

(continued)

Commodity	Fortification (ppm)	Interval (days)	Recovery (percent)
Sunflower Seed	0.05	0	101, 103
		31	86, 79
		61	92, 92
		124	77, 85
		215	70, 81
		335	76, 74

The results indicate that residues of trifluralin are stable in wheat forage, wheat straw, cottonseed, and soybean oil stored for 554 days, corn grain stored for 192 days, garlic stored for 79 days, peas stored for 272 days, and carrots stored for 90 days at -15 °C. Residues were stable for 125, 62, and 60 days of frozen storage in or on grapes, sugarcane, and turnip greens, respectively, although residues declined 20-30 percent at 180, 124, and 119 days. Residues declined ca. 20-30 percent in potatoes stored for 188 days, green hops stored for 120 days, cabbage stored for >60 days, plums stored for 180 days, cantaloupes stored for 60 days, sunflower seeds stored for >60 days, dry beans stored for >30 days, and alfalfa hay stored for >60 days. Residues declined ca. 35 percent in peanut nutmeats after 120 days. Residues were not stable in or on flax seed or wheat grain, decreasing ca. 40-50 percent at the first analysis interval.

Depending on the commodity and storage intervals and conditions, some residue data may need to be corrected for decline during storage, and the conclusion made previously that storage stability data are not needed for samples stored at room temperature for 4 months or frozen for 10 months may no longer be valid in all cases. Since considerable residue decline was noted in wheat grain and flax seed at the earliest sampling and analysis intervals, these commodities should in the future be analyzed immediately after harvest or immediately frozen and concurrent storage stability tests conducted.

MAGNITUDE OF THE RESIDUE IN PLANTS

Conclusions:

The Trifluralin Guidance Document (April, 1987) required data concerning the residues in processed products of the following: potatoes, sugar beets, soybeans, oranges, flax, cottonseed, peanuts, peppermint, spearmint, sugar cane, and sunflower seeds. In addition, the Guidance Document required additional residue data for corn, sorghum, wheat, field corn (forage, fodder and silage), alfalfa, flax, cottonseed, peanuts (vines and hay), peppermint and spearmint spent hay, sugar cane, and sunflower forage.

The Residue Chemistry Chapter dated July 3, 1985 indicated that the established crop group tolerance for "grain crops (except fresh corn and rice grain)" is not appropriate because there

are no registered uses for rice and the use directions are not uniform for the representative commodities of this group. Also indicated was the inappropriateness of the group tolerance for forage, fodder, and straw of the cereal grains group because the use directions are not uniform for the representative commodities of this group, and additional data must be submitted for field corn forage fodder and silage. Additionally, the Guidance Document indicated that the tolerances for residues in or on straw of wheat and barley should be increased to 0.1 ppm, and a tolerance of 0.1 ppm should be proposed for residues in or on wheat hay. The registrant must propose pregrazing and prefeeding intervals for peanuts, separate tolerances for residues in or on peanut vines and hay must be established and the tolerance for residues in or on members of the now-obsolete forage legumes group should be deleted, or alternatively, grazing and feeding restrictions may be proposed. A tolerance must be proposed for residues in or on sugar cane forage or the registrant may propose a grazing restriction. The 40 CFR listing "nuts" should be changed to the appropriate current commodity group name, "Tree Nuts." A separate tolerance of 0.05 ppm should be proposed for residues of trifluralin in or on almond hulls.

No registered use exists for upland cress; therefore, this tolerance should be revoked.

The use patterns discussed in this Residue Chemistry update are based on the following DowElanco labels: 10% G (EPA Reg No. 62719-131), 4 lb/gal EC (EPA Reg No. 62719-93, and EPA Reg No. 62719-116), and 5 lb/gal EC (EPA Reg No. 62719-118). When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that <u>all</u> end-use product labels (e.g., any unamended basic producer labels, SLNs, and products covered under the generic data exemption) be amended such that they are consistent with the amended basic producer labels.

<u>Non-grass Animal Feeds Group</u>

<u>Alfalfa hay</u>

<u>Tolerances</u>:

A tolerance of 0.2 ppm has been established for residues of trifluralin in or on alfalfa hay (40 CFR §180.207).

<u>Use direction and limitations</u>:

The 4 lb/gal EC formulation is registered for soil applications to established alfalfa at 0.75-1 lb ai/A, depending on the soil type. Applications may be made using ground or aerial equipment and incorporation into the soil must follow. There is no established PHI. No maximum seasonal use rate has been established. These use directions were obtained from the product label for the DowElanco 4 lb/gal EC formulation (EPA Reg. No. 62719-93). They are representative of the registered uses of the 5 lb/gal EC formulation.

The 10% G formulation (EPA Reg. No. 62719-131) is also registered for soil applications to established alfalfa at 2 lbs ai/A for all soil types. Applications are made using ground equipment, followed by 0.5 inches of rainfall (or irrigation) or incorporation into the soil. There is no established PHI. No maximum seasonal use rate has been established. These use directions were obtained from the product label for the DowElanco 10% G formulation (EPA Reg. No. 62719-131).

Conclusions:

The Trifluralin Guidance Document dated April, 1987 required data depicting trifluralin residues in or on alfalfa forage and alfalfa hay (dried to 10% water content) following a single postemergence application to established alfalfa with a G and EC formulation (in separate tests) at 1 lb/A. Samples were to be obtained on the day of treatment and at regular intervals thereafter to elucidate the pattern of residue decline (this information was needed to determine the necessity of a PHI or pregrazing interval). Tests were required to be conducted in CA, MN, and NY OR PA since these States represent the major U.S. alfalfa production regions (Agricultural Statistics, 1984, p. 247). In addition, data were required reflecting residues in or on seed processed from alfalfa hay bearing measurable weathered residues (using exaggerated rates, if necessary, to obtain measurable residues). Since multiple cuttings may be obtained from established alfalfa fields, the registrant was required to propose a label amendment specifying the maximum number of applications permitted per year.

Older available data, not reviewed for the Guidance Document (1984; MRID 00143667 and 1985; MRID 00155395) indicated that the residues of trifluralin were 0.004-0.028 ppm in or on alfalfa hay collected from first, second, and third cuttings made 30-195 days after treatment and were nondetectable (<0.002 or <0.003) to 0.223 ppm in or on alfalfa hay collected from first, second, and third cuttings made 13-92 days after treatment. However, Geographic representation was inadequate and a tolerance is needed for alfalfa forage.

The following are required:

- The registrant must propose a tolerance for alfalfa forage and submit appropriate residue data for this commodity. The registrant must also submit residue data for alfalfa hay from studies conducted in WI. The registrant must propose a PHI and the data used to support established or proposed tolerances must reflect this interval. A maximum number of applications per season or a maximum seasonal use rate must be proposed, and all pertinent labels should be changed to reflect these restrictions. All storage conditions and intervals should be submitted for the data requested.

References (used):

MRIDs: 00143667. 00155395.

Discussion of the data:

DowElanco (1984; MRID 00143667) submitted data from nine tests conducted in CA(3), NM(2), and KS(4) pertaining to residues of trifluralin in or on alfalfa hay. In these studies, the 10% G, and 4 and 5 lb/gal EC formulations were used to make surface applications or over-top-spray applications. Applications were made at the dormant stage or just after cutting at 1.8-2 lb ai/A (ca. 2x). Samples were collected from first, second, and third cuttings made 30-195 days after treatment. Samples were stored frozen for up to 26 days prior to analysis.

Analysis of 24 samples showed residues of trifluralin were 0.004-0.028 ppm. The highest level of residue was found in the trials conducted in KA following application of the granular formulation. Apparent residues in or on control samples were <0.003 (nondetectable)-0.013 ppm, where 15 of the 16 controls reported contained residues >0.003 ppm (the reported detection limit).

Residues were analyzed using Eli Lilly Method AM-AA-CA-RO23-AA-755. The method uses GC analysis with electron capture detection. The limit of detection was reported to be 0.003 ppm. In addition, the registrant reported a limit of quantitation of 0.008 ppm. Recoveries were 81-108% from samples fortified at 0.04 ppm. The registrant stated that storage stability samples were assayed along with the samples and recoveries ranged from 96-112% for samples stored at -20 °C; however, no actual data were submitted.

In addition, DowElanco submitted data (1985; MRID 00155395) from six tests conducted in CA(1), CO(1), and KS(4) pertaining to residues of trifluralin in or on alfalfa hay. In these studies, EC formulations were applied by chemigation at 2 lb ai/A (2x) at the first irrigation. Samples were collected from first, second, and third cuttings made 13-92 days after treatment. Samples were stored frozen for up to 211 days prior to analysis.

Residue levels were below the limit of detection for all of the third cutting samples except one, which contained residues of 0.017 ppm. Residues in the remaining samples were nondetectable (0.002-0.003 ppm)-0.223 ppm. The total number of samples analyzed was 17. The highest residue reported was found in a sample harvested 13 days after application (0.223 ppm) in KS; however, a sample from an identical experiment conducted in the same area contained residues of only 0.069 ppm. The registrant concludes that the high value is inconsistant with the remainder of the data provided. Apparent residues in control samples ranged from nondetectable (0.002-0.003) to 0.018 ppm where three of the 17 controls reported contained residues greater than the reported detection limit (0.002-0.003 ppm).

Residues were analyzed using Eli Lilly Method AM-AA-CA-RO23-AA-755. The limit of detection was reported to be 0.002-0.003 ppm. Recoveries were 68-103% from samples

fortified at 0.04 ppm. The registrant stated that storage stability samples were assayed along with the samples and recoveries ranged from 76-108% after storage of from 55-129 days at -20 °C.

The moisture content of each sample was determined by loss on drying in an oven operating at 105 °C. The residues were corrected and reported at 20% moisture content.

The geographic representation is not adequate. The tests states of CA(8%), CO(3%), KS(4%), NM(2%) and neighboring states of MO(2%), IA(7%), OR(2%), NV(2%), UT(2%), WY(2%), NE(5%), OK(2%), and AZ(2%) accounted for only 43% of the 1989 U.S. alfalfa production (Agricultural Statistics, 1990, p. 231). Additional data should be submitted for WI(9%). This will increase the geographic representation to approximately 70% of the U.S. production if neighboring states of MN(6%), MI(6%) and IL(4%) are included. The data submitted indicate that the residues of trifluralin did not exceed the established tolerances in or on alfalfa hay harvested at least 13 days following registered applications. Additional data and a tolerance proposal are needed for alfalfa forage.

Miscellaneous Commodities

Sugarcane

Tolerance:

A tolerance of 0.05 ppm has been established for residues of trifluralin in sugarcane (40 CFR §180.207).

Use directions and limitations:

The 4 lb/gal EC formulation is registered for soil application and incorporation twice a year for the pre-emergence control of annual grasses and broadleaf weeds in sugarcane at 1-2 lb ai/A using ground or aerial equipment. There is no established PHI. Applications should be made in the fall immediately after the seed pieces are planted and in the spring before or shortly after the cane emerges. In LA and TX, an alternate application method is permitted in which the mixture is applied 1-2 lb ai/A (for all soil textures) in the spring only, during a period ranging from before or shortly after the cane emerges up to layby. Applications are permitted to control Raoulgrass, in LA only, at 2 lb ai/A using the directions given for the layby application in LA or TX. In HI, applications should be made after planting (for plant cane) or after harvest (for ratoon cane) before weeds and cane emerge at 3-4 lbs ai/A for all soil textures. These use directions were obtained from the product label for the DowElanco 4 lb/gal EC formulation (EPA Reg. No. 62719-93). They are representative of the other registered uses for sugarcane.

Conclusions:

The Trifluralin Guidance Document dated April, 1987 required residue data on sugarcane from tests conducted in LA and TX. In addition, the Guidance Document required data depicting trifluralin residues in molasses, refined sugar, and bagasse processed from treated sugarcane bearing measurable trifluralin residues. The Guidance Document specified that a tolerance be proposed for residues in or on forage. Alternately, the registrant could propose a grazing restriction.

In response to these requirements, DowElanco Inc. submitted data (1989; MRID 41306701) concerning the magnitude of the residue in sugarcane from field trials conducted in LA and from studies concerning the processed commodities of sugarcane. Residues in or on the sugarcane from the field trials were all <0.01 ppm (nondetectable) even at exaggerated rates (2x and 5x). Since the Guidance Document required that the processing study be carried out using sugarcane bearing measurable residues, a sample was used from the test plot surviving the highest rate of application. The residues detected in or on each of the processed commodities were all <0.01 ppm (nondetectable). These data indicate that food/feed additive tolerances are not needed for sugarcane processed commodities. The requirement for a tolerance for sugarcane forage remains outstanding.

The following additional data are required:

- The registrant must propose a tolerance for residues in or on sugarcane forage, or alternatively, they may propose a grazing restriction. Storage conditions and intervals should be submitted for the data requested.

References (used):

MRID: 41306701.

Discussion of the Data:

DowElanco submitted data (1989; MRID 41306701) from one test conducted in LA depicting residues of trifluralin in or on sugarcane, and concerning sugarcane processed commodities (bagasse, raw sugar, and molasses). Applications were made in the fall and spring using the 4 lb/gal EC trifluralin formulation at 2, 4 and 10 lb ai/A (1, 2, and 5x). The final application was made 185 days before harvest. Samples were stored frozen for up to 80 days prior to analysis.

Residue levels were <0.01 ppm (nondetectable) in or on all four samples of sugarcane including the control. Since the Guidance Document required that the processing study be carried out using sugarcane bearing measurable residues, a sample was used from the test plot surviving the highest rate of application. The residues detected in or on each of the processed commodities were all <0.01 ppm (nondetectable).

Residues were analyzed using gas chromatography with electron capture detection, a method similar to Eli-Lilly method AM-AA-CA-RO23-AA-755. The limit of detection was 0.01 ppm for all of the commodities. Apparent residues on control samples were <0.01 ppm (nondetectable). Recoveries were 72% and 80% for sugarcane fortified at 0.01 ppm and 0.05 ppm, respectively. The processed commodities were fortified at 0.01 ppm, 0.05 ppm, and 0.1 ppm. The recoveries ranged from 77% to 89% for bagasse, 85% to 96% for molasses, and 89% to 97% for sugar. The data submitted indicate that the residues of trifluralin did not exceed the established tolerance in or on sugarcane harvested 185 days following registered applications. However, either a tolerance for forage or a grazing restriction must be proposed.

The geographic representation was adequate; the test state of LA is representative of the region where testing was required. The available data indicate that residues did not concentrate in bagasse, molasses, or sugar processed from cane treated at 5x the maximum registered rate. No additional data are required regarding sugarcane processed commodities. The requirement for a tolerance for sugarcane forage remains outstanding.

MAGNITUDE OF THE RESIDUE IN ANIMALS

Conclusions:

The Trifluralin Guidance Document dated April, 1987 did not require data concerning the magnitude of the residue in meat, milk, poultry, or eggs, because the nature of the residue in animals had not yet been adequately defined. The nature of the residue in animals has since been deemed adequate. However, no tolerances presently exist for residues of trifluralin in animal products. On receipt of the data requested in the sections entitled "Residue Analytical Methods" and "Magnitude of the Residues Plants" the need for appropriate feeding studies will be determined.

References (used):

N/A.

Discussion of the data:

N/A.

MASTER RECORD IDENTIFICATION NUMBERS

A summary of the subject memoranda and their associated MRID documents is presented below. The MRID documents cited were not included in the Pesticide Data Management System search conducted on December 14, 1990.

AGENCY MEMORANDA

CBRS No. 5927
Subject: Elanco Response to the Trifluralin Reregistration Standard: Animal Metabolism Studies.
From: R. D. Schmitt
Dated: November 14, 1989
MRID(s): 41233100. 41233101. 41233102.

CBRS No. 6568
Subject: Trifluralin Registration Standard Follow-up: DowElanco Submission of Feeding Level Data for Ruminant and Poultry Metabolism Studies.
From: E. T. Haeberer
Dated: April 16, 1990
MRID(s): none.

CBRS No. 5644
Subject: Trifluralin Registration Standard Follow-up: Response to Residue Chemistry Data Requirements on Plant Metabolism.
From: E. T. Haeberer
Dated: October 6, 1989
MRID(s): 41179001. 41179002.

CBRS No. 6432
Subject: Trifluralin Registration Standard Follow-up: Response to Data Deficiencies in Plant Metabolism Studies for Corn and Mustard.
From: E. T. Haeberer
Dated: March 16, 1990
MRID(s): 41396801. 41396802.

CBRS No. none.
Subject: Updating Trifluralin PAM II Method A to Method III.
From: F. D. Griffith
Dated: June 20, 1986
MRID(s): none.

47

CBRS No. none.
Subject: Trifluralin Registration Standard Follow-up. CBRS Response to Elanco Letter Dated July 21, 1989.
From: S. Willett
Dated: October 17, 1989
MRID(s): none.

MRID documents containing data which have been previously reviewed by the Agency are designated in bold print in the following bibliographic listing of Residue Chemistry Citations (used). The following citations were listed in the Pesticide Data Management System search conducted on December 14, 1990.

References (used):

00143667 Decker, O. (1984) Trifluralin Residue Data on Alfalfa following Application on Treflan for Weed Control: Report No. ODD8412. Unpublished study prepared by Elanco Product, Div. of Eli Lilly and Co. 61 p.

00155395 Decker, O. (1985) Trifluralin Residue on Alfalfa following Application of Treflan 5 EC or Treflan MTF by Chemigation for Weed Control: Study No. ODD8514. Unpublished study prepared by Elanco Product, Div. of Eli Lilly and Co. 66 p.

41233102 Magnussen, J. (1989) Nature of ^{14}C trifluralin Residues in Bovine Milk and Tissue: Project ID : Experiments ABC-0378, 0391, and 0412. Unpublished study prepared by Lilly Research Laboratories. 51 p.

41306701 Jacobson, B: Gresham, M. (1989) Trifluralin--Magnitude of the Residue in Sugarcane Commodities: Lab Project Number: 36477. Unpublished Study prepared by Analytical Bio-Chemistry Laboratories, Inc. 59 p.

41335901 Gresham, M. (1989) Freezer Stability for Trifluralin in Plant Matrices: ABC Final Report 36598; Method AM-AA-CA-RO23-AA-&%%; RST-8704-2. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 69 p.

48

TABLE A. GENERIC DATA REQUIREMENTS FOR TRIFLURALIN RESIDUE CHEMISTRY.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this Requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.240 Residue Chemistry				
171-2. Chemical Identity[4]	TGAI			
171-3. Directions for Use[5]	--	Partially	Product labels	Yes
171-4. Nature of Residue (Metabolism)				
Plants	PAIRA	Yes	41179001 41179002 41396801 41396802	No
Livestock	PAIRA & Plant Metabolites	Yes	41233101 41233102 41286101	No
171-4. Residue Analytical Method				
Plant residues	TGAI & Metabolites	Yes	N/A	No
Animal residues	TGAI & Metabolites	Partially	N/A	Yes[6]
171-4. Storage Stability Data	PAI	Partially	41335901	Yes[7]
171-4. Magnitude of the Residue - Residue Studies				

(Continued, footnotes follow)

TABLE A. (continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this Requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Root and Tuber Vegetables[8]				
- Carrots	TEP	Yes	N/A	No
- Potatoes	TEP	Yes	N/A	No
(processed commodities)	TEP	No	N/A	Yes[9]
- Sugar Beets	TEP	Yes	N/A	No
(processed commodities)	TEP	No	N/A	Yes[10]
- Turnips	TEP	Yes	N/A	No
Leaves of Root & Tuber Vegetables	TEP	Yes	N/A	No
- Turnip Tops	TEP	Yes	N/A	No
Bulb Vegetables[11]				
- Garlic	TEP	Yes	N/A	No
- Onions (dry bulb)	TEP	Yes	N/A	No
Leafy Vegetables[12]				
- Celery	TEP	Yes	N/A	No
- Upland Cress	TEP	No	N/A	Yes[13]
Brassica Leafy Vegetables				

(Continued, footnotes follow)

TABLE A. (continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this Requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
- Broccoli	TEP	Yes	N/A	No
- Brussels Sprouts	TEP	Yes	N/A	No
- Cabbage	TEP	Yes	N/A	No
- Cauliflower	TEP	Yes	N/A	No
- Collards	TEP	Yes	N/A	No
- Kale	TEP	Yes	N/A	No
- Mustard Greens	TEP	Yes	N/A	No
Legume Vegetables (succulent or dried)				
- Adzuki Beans	TEP	Yes	N/A	No
- Beans, Dried	TEP	Yes	N/A	No
- Field Peas (Cowpeas, Black-eyed peas)	TEP	Yes	N/A	No
- Guar Beans	TEP	Yes	N/A	No
- Lima Beans	TEP	Yes	N/A	No
- Mung Beans	TEP	Yes	N/A	No
- Peas (Succulent and Dried)	TEP	Yes	N/A	No

(Continued, footnotes follow)

TABLE A. (continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this Requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
- Snap Beans	TEP	Yes	N/A	No
- Soybeans	TEP	Yes	N/A	No
- (processed commodities)	TEP	No	N/A	Yes[14]
Foliage of Legume Vegetables				
- Bean vines and hay	TEP	Yes	N/A	No
- Pea vines and straw	TEP	Yes	N/A	No
- Soybean Forage, Hay, and Straw	TEP	Yes	N/A	No
Fruiting Vegetables(Except Cucurbits)				
- Peppers	TEP	Yes	N/A	No
- Tomatoes	TEP	Yes	N/A	No
Cucurbit Vegetables[15]				
- Cantaloupes	TEP	Yes	N/A	No
- Cucumbers	TEP	Yes	N/A	No
- Watermelons	TEP	Yes	N/A	No
Citrus Fruits				
- Grapefruit	TEP	Yes	N/A	No

(Continued, footnotes follow)

TABLE A. (continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this Requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
- Lemons	TEP	Yes	N/A	No
- Oranges	TEP	Yes	N/A	No
(processed commodities)	TEP	No	N/A	Yes[16]
- Tangeloes	TEP	Yes	N/A	No
- Tangerines	TEP	Yes	N/A	No
Stone Fruits[17]				
- Apricots	TEP	Yes	N/A	No
- Nectarines	TEP	Yes	N/A	No
- Peaches	TEP	Yes	N/A	No
- Plums	TEP	Yes	N/A	No
Small Fruits and Berries				
- Grapes	TEP	Yes	N/A	No
Tree Nuts				
- Almonds	TEP	Yes	N/A	No
- Pecans	TEP	Yes	N/A	No
- Walnuts	TEP	Yes	N/A	No

(Continued, footnotes follow)

TABLE A. (continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this Requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Cereal Grains[18]				
- Barley	TEP	Yes	N/A	No
- Corn, field	TEP	Partially	N/A	Yes[19]
(processed commodities)	TEP	No	N/A	Yes[20]
- Sorghum	TEP	Yes	N/A	No
(processed commodities)	TEP	No	N/A	Yes[21]
- Wheat	TEP	Yes	N/A	No
(processed commodities)	TEP	No	N/A	Yes[22]
Forage, Fodder, and Straw of Cereal Grains				
- Barley Forage, Hay, and Straw	TEP	Yes	N/A	No
- Corn Forage, Fodder and Silage	TEP	No	N/A	Yes[23]
- Sorghum Forage, Fodder, Silage, and Hay	TEP	Partially	N/A	No[24]
- Wheat Forage, Hay, and Straw	TEP	Partially	N/A	Yes[25]
Nongrass Animal Feeds				
- Alfalfa Forage and Hay	TEP	Partially	N/A	Yes[26]

(Continued, footnotes follow)

TABLE A. (continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this Requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Miscellaneous Commodities				
- Asparagus	TEP	Yes	N/A	No
- Flax	TEP	Partially	N/A	Yes[27]
- Cottonseed	TEP	Partially	N/A	Yes[28]
- Hops	TEP	Yes	N/A	No
- Mustard Seed	TEP	Partially	N/A	Yes[29]
- Peanuts	TEP	Partially	N/A	Yes[30]
- Peppermint	TEP	Partially	N/A	Yes[31]
- Rape Seed	TEP	Yes	N/A	No
- Safflower Seed	TEP	Yes	N/A	No
- Spearmint	TEP	Partially	N/A	Yes[32]
- Sugarcane	TEP	Partially	N/A	Yes[33]
- Sunflower Seed and Forage	TEP	Partially	N/A	Yes[34]
171-4. Meat/Milk; Poultry/Eggs	TGAI or Plant Metabolites	Partially	N/A	Reserved[35]

(Continued, footnotes follow)

TABLE A. (continued)

1 The requirements stated in this table are based on current Agency policy regarding residues of trifluralin to be regulated and conclusions of Chemistry Branch II/Reregistration Section with respect to the registrant's proposed protocols.

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

3 These references were submitted in response to the Trifluralin Guidance Document dated April, 1987. Underlining indicates documents that have been reviewed for this update.

4 The same chemical identity data are required as under 40 CFR §158.150-190, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables. Key: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; PAI = Pure active ingredient; EP = End-use product; TEP = Typical end-use product.

5 The use patterns discussed in this Residue Chemistry update are based on the following DowElanco labels: 10% G (EPA Reg No. 62719-131), 4 lb/gal EC (EPA Reg No. 62719-93, and EPA Reg No. 62719-116), and 5 lb/gal EC (EPA Reg No. 62719-118). When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., any unamended basic producer labels, SLNs, and products covered under the generic data exemption) be amended such that they are consistent with the amended basic producer labels.

6 At the present time, no tolerances exist for trifluralin residues in animal commodities. The poultry and ruminant metabolism studies indicate that residues of trifluralin should be regulated in meat, milk, poultry, and eggs. Thus, validated analytical methods for data collection and tolerance enforcement are required. Residue analytical methods suitable for data collection and tolerance enforcement must be submitted for determination of trifluralin in ruminant and poultry tissues, milk, and eggs.

7 DowElanco submitted data pertaining to the storage stability of trifluralin residues in or on 24 crop matrices. Depending on the intervals and conditions of sample storage, corrections for residue decline during storage may be needed for residues in or on grapes, sugarcane, turnip greens, cabbage, cantaloupe, potatoes, plums, green hops, alfalfa hay, sunflower seeds, peanut nutmeats, peanut hulls, and dry beans. Storage data are required in support of all required and previously submitted residue studies, reflecting the actual storage conditions and intervals for samples used to generate the residue data.

TABLE A. (continued)

8 To support a crop group tolerance, DowElanco proposes to conduct a total of five field trials on radishes in CA, FL, and MI. CBRS indicated that radish field trials need only be conducted in CA and FL, and that four trials will be adequate (CBRS memo by S. Willett dated October 17, 1989). The registrant must propose uses and submit data depicting residues in or on radishes treated according to the proposed uses. Tests must be conducted in CA and FL. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

9 DowElanco proposes to conduct a total of eight field trials on potatoes in ID, CA, ND, WA, ME, MN, and CO or MI. CBRS indicated that since adequate residue data are available, and since data are only required for potato processed commodities in order to determine if food/feed additive tolerances are needed, geographical representation is not necessary (CBRS memo by S. Willett dated October 17, 1989). CBRS concluded that a single field trial resulting in measurable weathered residues in the raw agricultural commodity will provide adequate samples for processing. The registrant must submit residue data for processed potato commodities (chips, granules, and dried potatoes) processed from potatoes bearing measurable, weathered residues. Should residues concentrate upon processing, appropriate food/feed additive tolerances may be indicated. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

10 DowElanco proposes to conduct a total of five field trials on sugar beets in CA, MN, ID, ND, and MI. CBRS indicated that adequate residue data are available for sugar beets. Since data are only required for sugar beet processed commodities, a single field trial resulting in measurable weathered residues in the raw agricultural commodity will provide adequate samples for processing (CBRS memo by S. Willett dated October 17, 1989). The registrant must submit residue data from dehydrated pulp, molasses, and refined sugar, processed from sugar beets bearing measurable, weathered residues. Should residues concentrate in processed products, appropriate food/feed additive tolerances may be indicated. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

11 To support a crop group tolerance, DowElanco proposes to conduct a total of three field trials on green onions in CA, TX, and AZ. CBRS has approved the number of tests and test locations (CBRS memo by S. Willett dated October 17, 1989). CBRS also indicated that data on green onions are needed if the registrant wishes to propose a group tolerance. If the registrant wishes to propose a group tolerance for bulb vegetables, they must propose uses for garlic and green onions, and residue data must be submitted depicting residues in or on green onions treated at the proposed rates, in CA, TX, and AZ. Storage data are required reflecting actual storage conditions and intervals for samples used to generate residue data.

TABLE A. (continued)

12 The Guidance Document indicated that the leafy vegetables (except Brassica) group tolerance is not appropriate unless residue data are submitted for lettuce (head and leaf) and spinach. Neither has the registrant submitted data in response to this requirement, nor have they petitioned the Agency to replace the group tolerance by separate tolerances. The registrant must submit residue data on lettuce (head and leaf) and spinach, and must propose uses for these crops for the group tolerance to be appropriate. The registrant may petition the Agency to replace the group tolerance by a separate tolerance for celery. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate residue data.

13 There is no registered use on upland cress. If the registrant wishes to support the established tolerance, they must propose use directions and submit appropriate residue data. Otherwise the tolerance will be revoked.

14 DowElanco proposes to conduct a total of three field trials on soybeans IL, IA, and MO. CBRS indicated that since adequate residue data are available, and since data are only required for commodities in order to determine if food/feed additive tolerances are needed, geographical representation is not necessary. CBRS concluded that a single field trial resulting in measurable weathered residues in the raw agricultural commodity will provide adequate samples for processing (CBRS memo by S. Willett dated October 17, 1989). The registrant must submit residue data for meal, hulls, crude oil, refined oil, and soapstock processed from soybeans bearing measurable, weathered residues. Should residues concentrate upon processing, appropriate food/feed additive tolerances may be indicated. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

15 To support a crop group tolerance, DowElanco proposes to conduct a total of six field trials on in CA, FL, TX, GA, NY, and NJ. CBRS has approved the number of tests and test locations (CBRS memo by S. Willett dated October 17, 1989). If the registrant wishes to propose a group tolerance for cucurbit vegetables, they must propose uses for summer squash, and residue data must be submitted depicting residues in or on summer squash treated at the proposed rates. Storage data are required reflecting actual storage conditions and intervals for samples used to generate residue data.

16 DowElanco proposes to conduct a total of two field trials on citrus in CA and FL. CBRS indicated that since adequate residue data are available, and since data are only required for commodities in order to determine if food/feed additive tolerances are needed, geographical representation is not necessary. CBRS concluded that a single field trial resulting in measurable weathered residues in the raw agricultural commodity will provide adequate samples for processing. The registrant must submit residue data for oil, molasses, and dehydrated pulp processed from citrus fruit bearing measurable, weathered residues. Should residues concentrate upon processing, appropriate food/feed additive tolerances may be

TABLE A. (continued)

indicated. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

17 To support a crop group tolerance, DowElanco proposes to conduct a total of five field trials on cherries in CA, MI, NY, and WA. CBRS indicated that the number and location of the proposed trials are adequate (CBRS memo by S. Willett dated October 17, 1989). The registrant must propose uses and submit data depicting residues in or on cherries treated according to the proposed uses. Tests must be conducted in CA, MI, NY, and WA. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

18 The crop group tolerance for grain crops (except fresh corn and rice grain) is inappropriate and should be revoked.

19 DowElanco proposes to conduct three field trials with field corn in OH, IA, and IL. CBRS indicated that the number and location of the proposed trials are adequate (CBRS memo by S. Willett dated October 17, 1989). Data are required depicting residues of trifluralin in or on corn grain harvested at the shortest posttreatment interval (consistent with good agricultural practice) following over-the-top application of an EC formulation at 1 lb ai/A. Tests are to be conducted in OH, IA, and IL.

20 The registrant intends to conduct a processing study with field corn. Data are required to show the concentration of residues of trifluralin in grits, meal, flour, and grain dust processed from corn grain bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

21 The registrant must conduct a processing study with sorghum. Data are required to show the concentration of trifluralin in flour, starch, and grain dust processed from grain bearing measurable weathered residues. If residues concentrate in either commodity, an appropriate food/feed additive tolerance must be proposed.

22 The registrant must conduct a processing study with wheat. Data are required to show the concentration of trifluralin in bran, flour, middlings, shorts, and grain dust processed from grain bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate feed additive tolerance must be proposed.

23 DowElanco proposes to conduct three field trials with field corn in OH, IA, and IL. CBRS indicated that the number and location of the proposed trials are adequate (CBRS memo by S. Willett dated October 17, 1989). Data are required depicting residues of trifluralin in or on corn forage and fodder harvested at the shortest posttreatment interval (consistent

TABLE A. (continued)

with good agricultural practice) following over-the-top application of an EC formulation at 1 lb ai/A. Tests are to be conducted in OH, IA, and IL.

24 CBRS has determined that data may be translated from corn forage and fodder to sorghum forage and fodder (CBRS memo by S. Willett dated October 17, 1989).

25 As stated in the Guidance Document, the tolerance for residues in or on straw should be increased to 0.1 ppm and a tolerance needs to be proposed for hay at the same level.

26 Older available data, not reviewed for the Guidance Document, were considered for adequacy to meet this requirement. However, geographic representation was inadequate. In addition, the registrant must propose a tolerance for alfalfa forage and submit appropriate residue data for this commodity. The registrant must also submit residue data for alfalfa hay from studies conducted in WI. The registrant must propose a PHI and the data used to support established or proposed tolerance must reflect this interval. A maximum number of applications per season or a maximum seasonal use rate must be proposed, and all pertinent labels should be changed to reflect these restrictions. All storage conditions and intervals should be submitted for the data requested.

27 The registrant's proposal to translate processing data from cottonseed to flax has been approved by CBRS (CBRS memo by S. Willett dated October 17, 1989). Data are required for flax straw. CBRS has recommended trials conducted in ND and/or SD.

28 DowElanco proposes to conduct a total of two field trials on cotton in MS and TX. CBRS indicated that the number and location of the proposed trials are adequate to generate the needed data on cotton forage (CBRS memo by S. Willett dated October 17, 1989). Data are required also depicting the potential for residue concentration in meal, hulls, crude oil, and refined oil processed from cottonseed bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

29 The Agency is requiring data depicting residues in or on seed from mustard receiving seed-crop use of trifluralin. It is recommended that two tests be conducted in any of the major mustard-seed producing areas (CBRS memo by S. Willett dated October 17, 1989).

TABLE A. (continued)

30 DowElanco proposes to conduct a total of two field trials on peanuts in MS and TX. CBRS indicated that the number and location of the proposed trials are adequate to generate the needed data on peanut forage (CBRS memo by S. Willett dated October 17, 1989). Data are required also depicting the potential for residue concentration in meal, hulls, crude oil, and refined oil processed from peanuts bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

31 DowElanco proposes to conduct two field trials on peppermint. CBRS indicated that since adequate residue data are available, and since data are only required for commodities in order to determine if food/feed additive tolerances are needed, geographical representation is not necessary. CBRS concluded that a single field trial resulting in measurable weathered residues in the raw agricultural commodity will provide adequate samples for processing. The registrant must submit residue data on oil and spent hay processed from mint bearing measurable, weathered residues. Should residues concentrate upon processing, appropriate food/feed additive tolerances may be indicated. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

32 DowElanco proposes to conduct two field trials on spearmint. CBRS indicated that since adequate residue data are available, and since data are only required for commodities in order to determine if food/feed additive tolerances are needed, geographical representation is not necessary. CBRS concluded that a single field trial resulting in measurable weathered residues in the raw agricultural commodity will provide adequate samples for processing. The registrant must submit residue data oil and spent hay processed from mint bearing measurable, weathered residues. Should residues concentrate upon processing, appropriate food/feed additive tolerances may be indicated. Storage data are required reflecting the actual storage conditions and intervals for samples used to generate the residue data.

33 DowElanco Inc. submitted data concerning the magnitude of the residue in sugarcane from field trials conducted in LA and from studies concerning the processed commodities of sugarcane. Residues in or on the sugarcane from the field trials were all <0.01 ppm (nondetectable) even at exaggerated rates (2x and 5x). The residues detected in or on each of the processed commodities representing the test plot surviving the highest rate of application were all <0.01 ppm (nondetectable). These data indicate that food/feed additive tolerances are not needed for sugarcane processed commodities. The registrant must propose a tolerance for residues in or on sugarcane forage, or alternatively, they may propose a grazing restriction. All storage conditions and intervals should be submitted for the data requested.

TABLE A. (continued)

34 DowElanco proposes to conduct a total of two field trials on sunflower in MS and TX. CBRS indicated that the number and location of the proposed trials are adequate to generate the needed data on sunflower forage (CBRS memo by S. Willett dated October 17, 1989). Data are required also depicting the potential for residue concentration in meal, hulls, crude oil, and refined oil processed from sunflower seed bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

35 The Trifluralin Guidance Document dated April, 1987 did not require data concerning the magnitude of the residue in meat, milk, poultry, or eggs, because the nature of the residue in animals had not yet been adequately defined. The nature of the residue in animals has since been deemed adequate. However, no tolerances presently exist for residues of trifluralin in animal products. On receipt of the data requested in the sections entitled "Residue Analytical Methods" and "Magnitude of the Residues Plants" the need for appropriate feeding studies will be determined.

TABLE B. (Continued)

[4]DowElanco has responded to the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) regarding product identity and composition for the trifluralin 95% T (EPA Reg. No. 62179-99). The data provided do not satisfy the requirements pertaining to product composition because the data do not cover the most recent manufacturing process. Nominal concentration must be provided for all ingredients present at ≥0.1% by weight. Additional data are required for the 95% T (EPA Reg. No. 62719-99).

DowElanco has responded to the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) regarding product identity and composition for the trifluralin 44.5% FI (EPA Reg. No. 62719-101), 20% FI (EPA Reg. No. 62719-133) and 50.8% FI (EPA Reg. No. 62719-172). The data submitted do not fully satisfy the requirements. Nominal concentration of the impurities resulting from the technical product must be provided and included on the Confidential Statement of Formula of the 44.5% FI (EPA Reg. No. 62719-101), 20% FI (EPA Reg. No. 62719-133) and 50.8% FI (EPA Reg. No. 62719-172). Additional data are required for these three formulation intermediates.

[5]DowElanco has responded to the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) regarding the starting materials used and manufacturing process for the trifluralin 95% T (EPA Reg. No. 62719-99). The information provided does not fully satisfy the requirements. The registrant must discuss its most recent technical trifluralin manufacturing process. The registrant must submit a revised list of starting materials and description of the production process. Additional data are required.

DowElanco has responded to the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) regarding the starting materials used and manufacturing process for the trifluralin 44.5% FI (EPA Reg. No. 62719-101). The information provided does not fully satisfy the requirements. Technical specifications of the inerts and solvents, duration of the manufacturing process and detailed description of the equipment and packaging materials used must be provided. Additional information is required.

DowElanco has responded to the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) regarding the starting materials used and manufacturing process for the trifluralin 20% FI (EPA Reg. No. 62719-133). The information provided does not fully satisfy the requirements. Technical specifications of the inerts, duration of the manufacturing process and description of packaging materials must be provided. Additional information is required.

DowElanco has responded to the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) regarding the starting materials used and manufacturing process for the trifluralin 50.8% FI (EPA Reg. No. 62719-172). The information provided does not fully satisfy the requirements. Technical specifications of the starting materials and detailed description of the

TABLE B. (Continued)

manufacturing process must be provided. Additional information is required.

[6]DowElanco has responded to the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) regarding a discussion of the formation of impurities in the trifluralin 95% T (EPA Reg. No. 62719-99). The data provided do not fully satisfy the requirements. The registrant does not cover the most recent manufacturing process for the trifluralin 95% T. A revised discussion of impurity formation based on the most recent manufacturing process must be provided. Additional information is required.

The registrant referred to technical trifluralin discussion of formation of impurities and claimed that no additional impurities are formed during the manufacturing process of all three formulation intermediates. Since the information provided for the technical trifluralin does not fully satisfy the requirement of 40 CFR §158.167, additional information is also required for the 44.5% FI, 20% FI and 50.8% FI.

[7]DowElanco has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis for the trifluralin 95% T (EPA Reg. No. 62719-99). The data submitted are not pertinent to products from its most recent technical trifluralin manufacturing process. New analytical results must be submitted for this product, including total nitrosamines. Additional data are required.

DowElanco has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis for each of the trifluralin 44.5% FI (EPA Reg. No. 62719-101) and 20% FI (EPA Reg. No. 62719-133). The data provided are not acceptable. Preliminary analysis based on five production batches of manufacturing use products is required. Use of laboratory simulated samples is not acceptable. This preliminary analysis must include the active ingredient, all intentionally added inerts, and total N-nitrosamines. Discussion of the two analytical methods AM-AA-CA-JO31-AB-755 and AM-AA-CA-J032-AB-755 used for the 44.5% FI analysis must be provided. Discussion of the two analytical methods AM-AA-CA-JO31-AB-755 and AM-AA-CA-J371-AA-755 used for the 20% FI analysis must be provided. Additional data are required for these two products.

Preliminary analysis data were not submitted for the DowElanco 50.8% FI (EPA Reg. No. 62719-172). All data pertaining to this topic are required for the 50.8% FI.

[8]DowElanco has responded to the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) regarding certified limits for the trifluralin 95% T (EPA Reg. No. 62719-99). The data provided do not cover DowElanco's most recent manufacturing process for its technical trifluralin. Data generated from the most recent manufacturing process must be provided. Certified limits must

TABLE B. (Continued)

be provided for all ingredients present at ≥0.1% by weight. Additional data are required for the 95% T.

Certified limits for the impurities resulting from the technical product are required for the 44.5% FI (EPA Reg. No. 62719-101), 20% FI (EPA Reg. No. 62719-133) and 50.8% FI (EPA Reg. No. 62719-172).

[9]DowElanco has responded to the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3) regarding enforcement analytical methods for the trifluralin 95% T (EPA Reg. No. 62719-99). The data provided do,nto fully satisfy the requirements. Validation data are required for the capillary gas chromatograph technique used to determine the volatile impurities in the 95% T. Additional data are required.

There were no enforcement analytical methods provided to determine and quantify the impurities resulting from the 95% T, for the 44.5%, 20% and 50.8% formulation intermediates (EPA Reg. Nos. 62719-101, -133, -172, respectively). Additional data are required for these three formulation intermediates.

[10]DowElanco has responded to the requirements of 40 CFR §158.190 for the trifluralin 95% T, 44.5% FI, 20% FI and 50.8% FI (EPA Reg. Nos. 62719-99, -101-, -133 and -172, respectively) regarding storage stability (Guideline Ref. No. 63-17). With the exception of 50.8% FI, the storage stability requirements for these products are fully met. The storage stability study of 50.8% in one gallon steel drums coated with ethoxy-phenolic lining simulating trade package is in progress. The Agency is waiting for these data to be submitted.

[11]N/A = not applicable.

[12]If samples are needed, the Agency will request them.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE AGAN TRIFLURALIN 98% TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Yes	40454701	No
61-3. Formation of Impurities	TGAI	Partially	40454701	Yes[4]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	40454701	Yes[5]
Physical and Chemical Characteristics[6]				
63-2. Color	TGAI	Yes	40454701	No
63-3. Physical State	TGAI	Yes	40454701	No
63-4. Odor	TGAI	Yes	40454701	No
63-5. Melting Point	TGAI	Yes	40454701	No
63-6. Boiling Point	TGAI	Yes	40454701	No

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	40454701	No
63-8. Solubility	TGAI or PAI	Yes	40454701	No
63-9. Vapor Pressure	TGAI or PAI	Yes	40454701	No
63-10. Dissociation Constant	TGAI or PAI	No	--	Yes[7]
63-11. Octanol/Water Partition Coefficient	PAI	Yes	40454701	No
63-12. pH	PAI or TGAI	Yes	40454701	No
63-13. Stability	TGAI	Partially	40454701	Yes[8]
Other Requirements				
64-1. Submittal of Samples	N/A	N/A[9]	N/A	Reserved[10]

[1]Data requirements pertain to the Agan Chemical Manufacturers, Ltd. trifluralin 98% T (EPA Reg. No. 11603-13). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Trifluralin Manufacturing Use Products".

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

[3]These references were submitted in response to the Trifluralin Guidance Document (4/87). Underlining indicates documents that have been reviewed for this update.

TABLE A. (Continued)

[4]Agan has responded to the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) regarding a discussion of the formation of impurities in the trifluralin 98% T (EPA Reg. No. 11603-13). The data provided do not fully satisfy the requirements. Post-production contamination must be discussed. Additional information is required.

[5]Agan has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis of trifluralin 98% T (EPA Reg. No. 11603-13). The data provided do not fully satisfy the requirements. N-nitrosamine analysis of the technical product, two of each, at initial production, three months and six months after production must be carried out. Additional data are required.

[6]Agan has responded to the requirements of 40 CFR §158.190 pertaining to the physical and chemical characteristics of trifluralin 98% T (EPA Reg. No. 11603-13). However, not all requirements are fully satisfied.

[7]Agan must provide the dissociation constant (Guideline Ref. No. 63-10) for the trifluralin 98% T (EPA Reg. No. 11603-13). Additional data are required.

[8]Agan has provided stability data (Guideline Ref. 63-13) for the trifluralin 98% T (EPA Reg. No. 11603-13). However, the data submitted was incomplete. Methods and storage conditions must be provided. Additional data are required.

[9]N/A = not applicable.

[10]If samples are needed, the Agency will request them.

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

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Identity and Disclosure of Ingredients	MP	Partially	40454701	Yes[6]
61-2. Beginning Materials and Production Process	MP	Yes	40454701	No
61-3. Formation of Impurities	MP	Partially	40454701	Yes[4]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	Partially	40454701	Yes[5]
62-2. Certification of Ingredient Limits	MP	Partially	40454701	Yes[6]
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	40454701 40692701	Yes[7]
Physical and Chemical Characteristics[8]				
63-2. Color	MP	Yes	40454701	No
63-3. Physical State	MP	Yes	40454701	No
63-4. Odor	MP	Yes	40454701	No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	40454701	No

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-12. pH	MP	Yes	40454701	No
63-14. Oxidizing or Reducing Action	MP	No	40454701	Yes[9]
63-15. Flammability	MP	Yes	40454701	No
63-16. Explodability	MP	No	40454701	Yes[9]
63-17. Storage Stability	MP	No	40454701	Yes[9]
63-18. Viscosity	MP	N/A[10]	--	N/A
63-19. Miscibility	MP	N/A	--	N/A
63-20. Corrosion Characteristics	MP	No	40454701	Yes[9]
Other Requirements				
64-1. Submittal of Samples	N/A	N/A	N/A	Reserved[11]

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

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

[3]These references were submitted in response to the Trifluralin Guidance Document (4/87). Underlining indicates documents that have been reviewed for this update.

TABLE B. (Continued)

[4]Agan has responded to the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) regarding a discussion for the formation of impurities in the trifluralin 98% T (EPA Reg. No. 11603-13). The information provided does not fully satisfy the requirements. The registrant must discuss post-production contamination. Additional information is required.

[5]Agan has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analyis of the trifluralin 98% T (EPA Reg. No. 11603-13). The data provided do not fully satisfy the requirements. Nitrosamine analysis, two of each, at initial production, three months after production and six months after production must be carried out by the registrant. Additional data are required.

[6]Agan has responded to the requirements of 40 CFR §158.155 and 158.175 (Guideline Ref. Nos. 61-1 and 62-2, respectively) regarding product identity and certified limits for the trifluralin 98% T (EPA Reg. No. 11603-13). The data provided do not fully satisfy the requirements. Upper certified limits for one impurity is exceeded by its nominal concentration. The registrant must explain the difference or revise the data for this particular impurity. Nominal concentrations and certified limits must be resubmitted on EPA Form 8570-4 (Rev. 2-85). Additional data are required.

[7]Agan has responded to the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3) regarding enforcement analytical methods for the trilfuralin 98% T (EPA Reg. No. 11603-13). The data provided do not fully satisfy the requirements. Only validation data for the nitrosamines at three stages were submitted by Agan Chemical Manufacturers, Ltd. Validation data for the analytical methods used to determine the impurities must be provided. Additional data are required.

[8]Agan has responded to some of the requirements of 40 CFR §158.190 regarding physical and chemical characteristics for the trifluralin 98% T (EPA Reg. No. 11603-13). However, not all data requirements have beeen satisfied.

[9]The following Agan data requirements remain outstanding: oxidizing/reducing action, explodability, storage stability and corrosion characteristics (Guideline Ref. Nos. 63-14, -16, -17 and -20, respectively). These characteristics are required since the trifluralin 98% T serves as a manufacturing-use product. Additional data are required for the Agan triluralin 98% T (EPA Reg. No. 11603-13).

[10]N/A = not applicable.

[11]If samples are required, the Agency will request them.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE INDUSTRIA PRODOTTI CHIMICI, S.P.A. TRIFLURALIN 96% TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Partially	40743901	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	40743901	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	40743902	Yes[6]
Physical and Chemical Characteristics				
63-2. Color	TGAI	Yes	40446902	No
63-3. Physical State	TGAI	Yes	40446902	No
63-4. Odor	TGAI	Yes	40446902	No
63-5. Melting Point	TGAI	Yes	40446902	No
63-6. Boiling Point	TGAI	N/A[7]	40446902	N/A

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	40446902	No
63-8. Solubility	TGAI or PAI	Yes	40446902	No
63-9. Vapor Pressure	TGAI or PAI	Yes	40446902	No
63-10. Dissociation Constant	TGAI or PAI	Yes	40446902	No
63-11. Octanol/Water Partition Coefficient	PAI	Yes	40446902	No
63-12. pH	PAI or TGAI	Yes	40446902	No
63-13. Stability	TGAI	Yes	40446902	No
Other Requirements				
64-1. Submittal of Samples	N/A	N/A	N/A	Reserved[8]

[1]Data requirements pertain to the Industria Prodotti Chimici, S.P.A. trifluralin 96% T (EPA Reg. No. 33660-3). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Trifluralin Manufacturing Use Products".

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

[3]These references were submitted in response to the Trifluralin Guidance Document (4/87). Underlining indicates documents that have been reviewed for this update.

TABLE A. (Continued)

[4]Industria Prodotti Chimici, S.P.A. which is represented by Pazzianos Associates has responded to the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) regarding the starting materials used and manufacturing process for the trifluralin 96% T (EPA Reg. No. 33660-3). The data provided do not fully satisfy the requirements. Relative amounts of the starting materials, technical specifications and source of some of the starting materials, duration of the manufacturing process, description of physical conditions (temperature, pressure), and detailed description of the equipment used must be provided. Inconsistencies regarding the use of one of the starting materials must be clarified. Additional information is required for this product.

[5]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) regarding a discussion of the formation of impurities in the trifluralin 96% T (EPA Reg. No. 33660-3). The information provided does not fully satisfy the requirements. Post-production contamination must be discussed. Additional information is required.

[6]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis of the trifluralin 96% T (EPA Reg. No. 33660-3). The data provided do not fully satisfy the requirements. The registrant must clarify if duplicate preliminary analysis of seven batches for impurities was carried out as it did for the active ingredient. The method used to [redacted] must be provided. Additional data are required.

[7]N/A = not applicable. QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

[8]If samples are needed, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE INDUSTRIA PRODOTTI CHIMICI, S.P.A. TRIFLURALIN MANUFACTURING-USE PRODUCTS.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Identity and Disclosure of Ingredients	MP	Partially	40743901	Yes[4]
61-2. Beginning Materials and Production Process	MP	Partially	40743901	Yes[5]
61-3. Formation of Impurities	MP	Partially	40743901	Yes[6]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	Partially	40743902	Yes[7]
62-2. Certification of Ingredient Limits	MP	Partially	40743902	Yes[8]
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	40743902	Yes[9]
Physical and Chemical Characteristics				
63-2. Color	MP	Yes	40446902	No
63-3. Physical State	MP	Yes	40446902	No
63-4. Odor	MP	Yes	40446902	No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	40446902	No

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-12. pH	MP	Yes	40446902	No
63-14. Oxidizing or Reducing Action	MP	Yes	40446902	No
63-15. Flammability	MP	N/A[10]	40446902	N/A
63-16. Explodability	MP	Yes	40446902	No
63-17. Storage Stability	MP	Yes	40834701	No
63-18. Viscosity	MP	N/A	40446902	N/A
63-19. Miscibility	MP	N/A	40446902	N/A
63-20. Corrosion Characteristics	MP	Yes	40446902	No
Other Requirements				
64-1. Submittal of Samples	N/A	N/A	N/A	Reserved[11]

[1]Data requirements pertain to Industria Prodotti Chimici, S.P.A. trifluralin 96% T (EPA Reg. No. 33660-3). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Trifluralin Technical Grade of the Active Ingredient".

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

[3]These references were submitted in response to the Trifluralin Guidance Document (4/87). Underlining indicates documents that have been reviewed for this update.

TABLE B. (Continued)

[4]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) regarding product identity and composition for the trifluralin 96% T (EPA Reg. No. 33660-3). The data provided do not fully satisfy the requirements. Nominal concentration and CAS Registry No. of the active ingredient, nominal concentration of impurities that are present at ≥0.1% by weight must be provided. All data must be reported on EPA Form 8570-4 (Rev. 2-85). Additional data are required.

[5]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR 158.160-165 (Guideline Ref. No. 61-2) regarding the starting materials used and manufacturing process for the trifluralin 96% T (EPA Reg. No. 33660-3). The information provided does not fully satisfy the requirements. Relative amounts of the starting materials, technical specifications and source of some of the starting materials, duration of the manufacturing process, description of physical conditions (temperature, pressure) and detailed description of the equipment used must be provided. Inconsistencies regarding the listing of one of the starting materials must be clarified. Additional information is required.

[6]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) regarding a discussion of the formation of impurities in the trifluralin 96% T (EPA Reg. No. 33660-3). The information provided does not fully satisfy the requirements. Post-production contamination must be discussed. Additional information is required.

[7]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis of the trifluralin 96% T (EPA Reg. No. 33660-3). The data provided do not fully satisfy the requirements. The registrant must clarify if duplicate preliminary analysis of seven batches for the impurities was carried out as it did for the active ingredient. The method used to [redacted] in the technical trifluralin must be provided. Additional data are required.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

[8]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) regarding certified limits for the trifluralin 96% T (EPA Reg. No. 33660-3). The data provided do not fully satisfy the requirements. Upper certified limit for the active ingredient must be provided. All certified limits should be reported on EPA Form 8570-4 (Rev. 2-85). Additional data are required.

[9]Industria Prodotti Chimici, S.P.A. has responded to the requirements of 40 CFR § 158.180 (Guideline Ref. No. 62-3) regarding enforcement analytical methods for the trifluralin 96% T (EPA Reg. No. 33660-3). The data provided do not fully satisfy the requirements. Validation data for the analytical methods used to determine the active ingredient and impurities must be provided. Additional data are required.

TABLE B. (Continued)

[10]N/A = not applicable.

[11]If samples are needed, the Agency will request them.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE DREXEL TRIFLURALIN 96% TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry[4]				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	No	--	Yes
61-3. Formation of Impurities	TGAI	No	--	Yes
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	No	--	Yes
Physical and Chemical Characteristics				
63-2. Color	TGAI	No	--	Yes
63-3. Physical State	TGAI	No	--	Yes
63-4. Odor	TGAI	No	--	Yes
63-5. Melting Point	TGAI	No	--	Yes
63-6. Boiling Point	TGAI	No	--	Yes

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-7. Density, Bulk Density, or Specific Gravity	TGAI	No	--	Yes
63-8. Solubility	TGAI or PAI	No	--	Yes
63-9. Vapor Pressure	TGAI or PAI	No	--	Yes
63-10. Dissociation Constant	TGAI or PAI	No	--	Yes
63-11. Octanol/Water Partition Coefficient	PAI	No	--	Yes
63-12. pH	TGAI	No	--	Yes
63-13. Stability	TGAI	No	--	Yes
Other Requirements				
64-1. Submittal of Samples	N/A	N/A	N/A	N/A

[1]Data requirements pertain to the Drexel trifluralin 96% T (EPA Reg. No. 19713-226). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Trifluralin Manufacturing Use Products".

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

[3]These references were submitted in response to the Trifluralin Guidance Document (4/87). Underlining indicates documents that have been reviewed for this update.

TABLE A. (Continued)

[4]All product chemistry data for the 61, 62 and 63 requirements must be provided for the Drexel trifluralin 96% T (EPA Reg. No. 19713-226).

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

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry[4]				
Product Composition				
61-1. Product Identity and Disclosure of Ingredients	MP	No		Yes
61-2. Beginning Materials and Production Process	MP	No		Yes
61-3. Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	No		Yes
62-2. Certification of Ingredient Limits	MP	No		Yes
62-3. Analytical Methods to Verify Certified Limits	MP	No		Yes
Physical and Chemical Characteristics				
63-2. Color	MP	No		Yes
63-3. Physical State	MP	No		Yes
63-4. Odor	MP	No		Yes
63-7. Density, Bulk Density, or Specific Gravity	MP	No		Yes

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-12. pH	MP	No		Yes
63-14. Oxidizing or Reducing Action	MP	No		Yes
63-15. Flammability	MP	No		Yes
63-16. Explodability	MP	No		Yes
63-17. Storage Stability	MP	No		Yes
63-18. Viscosity	MP	No		Yes
63-19. Miscibility	MP	No		Yes
63-20. Corrosion Characteristics	MP	No		Yes
Other Requirements				
64-1. Submittal of Samples	N/A	N/A	N/A	N/A

[1]Data requirements pertain to the Drexel Chemical Company trifluralin 96% T (EPA Reg. No. 19713-226). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Trifluralin Technical Grade of the Active Ingredient".

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

[3]These references were submitted in response to the Trifluralin Guidance Document (4/87). Underlining indicates documents that have been reviewed for this update.

TABLE B. (Continued)

[4]All product chemistry data for the 61, 62 and 63 requirements must be provided for the Drexel trifluralin 96% T (EPA Reg. No. 19713-226).

ATTACHMENT 3

TRIFLURALIN

(Chemical Code 036101)

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 17 Page(s)
Appendix B: 3 Page(s)
Appendix C: 8 Page(s)

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

8

trifluralin

Page_____ is not included in this copy.

Pages 87 through 114 are not included.

The material not included contains the following type of information:

X Identity of product inert ingredients.

X Identity of product impurities.

X Description of the product manufacturing process.

X 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.