10-12-94

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

OCT 12 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Trifluralin Reregistration.** Supplemental Product Chemistry Data for the I.Pi.Ci. Trifluralin 96% T (EPA Reg. No. 33660-3).
CBRS No.: 14012
DP Barcode No.: D205239
MRID No.: 43233001
Chemical No.: 036101
Reregistration Case No.: 0179

FROM: Bonnie Cropp-Kohlligian, Environmental Scientist
Chemistry Pilot Review Team
Chemistry Branch II: Reregistration Support
Health Effects Division [7509C]

THRU: Edward Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division [7509C]

TO: Walter Waldrop/Connie Childress [PM-71]
Reregistration Branch
Special Review and Reregistration Division [7508W]

Attached is a review of supplemental product chemistry data (MRID 43233001) submitted by Industria Prodotti Chimici S.P.A. (I.Pi.Ci.) in response to deficiencies identified in the Trifluralin Reregistration Standard Update (10/29/91) pertaining to the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3). This review was completed by Dynamac Corporation under supervision of CBRS/HED. This review has undergone secondary review in the branch and has been revised to reflect Agency policies.

CBRS concludes that the submitted data (MRID 43233001) satisfy data requirements pertaining to the discussion of the formation of impurities (GLN 61-3) and the preliminary analysis (GLN 62-1) for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3).

The submitted data (MRID 43233001) do not satisfy data requirements pertaining to product identity and disclosure of ingredients (GLN 61-1) and certified limits (GLN 62-2) for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3) because an impurity detected at greater than 0.1% in the preliminary analysis study reported in the Trifluralin Update was not included on the CSF. A nominal concentration must be included for this impurity. In addition, the nominal concentration listed for another impurity has been increased (approximately 10 fold) and is no longer representative of the preliminary analysis. The nominal concentration should be modified or an explanation of how this value was determined must be submitted.

The submitted data (MRID 43233001) do not satisfy data requirements pertaining to starting materials and the production process (GLN 61-2) for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3) because the registrant did not include the source for an intermediate which they stated may be purchased commercially rather than manufactured by I.Pi.Ci.

The submitted data (MRID 43233001) do not satisfy data requirements pertaining to enforcement analytical methods (GLN 62-3) for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3) because the concentration of a representative impurity in the standard solution mixture far exceeded the levels of the impurities it was intended to represent. If representative impurity standards are to be used for validation of the method then concentration ranges encompassing the typical impurity concentrations for which the standards are representative must be submitted.

If you need addition input please advise.

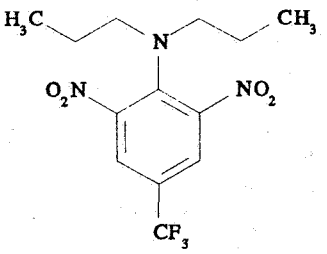
Attachment 1: Trifluralin Product Chemistry Review.
Attachment 2: Confidential Appendix for Trifluralin Product Chemistry.

cc (with Attachment 1 and 2): BLCKohlligian (CBRS), Trifluralin Registration Standard File, Trifluralin Update File, Trifluralin SF, Dynamac.

cc (with Attachment 1 only): RF, Circulation.

RDI: WSmith:10/3/94 PDeschamp:10/3/94 TEdwards:10/3/94 SKnizner:10/3/94 COlinger:10/3/94 MMetzger:10/6/94 EZager:10/6/94
7509C:CBRS:BLCKohlligian:CM#2:Rm 805B:703-305-7462:10/3/94.

TRIFLURALIN



Shaughnessy No. 036101; Case 0179

(CBRS No. 14012; DP Barcode D205239)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to the Trifluralin Reregistration Standard Update dated 10/29/91, Industria Prodotti Chimici S.P.A. (I.Pi.Ci.) has submitted a single volume of supplemental product chemistry data (D205239; CBRS No. 14012; 1994; MRID 43233001) for the 96% technical (T; EPA Reg. No. 33660-3). The submitted data and our conclusions are discussed below.

61-1. Product Identity and Disclosure of Ingredients

I.Pi.Ci. has submitted (1994; MRID 43233001) a Confidential Statement of Formula (CSF) dated 3/4/94 for the 96% T, which is presented in the Confidential Appendix. These data do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product identity for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3) because an impurity detected at greater than 0.1% in the preliminary analysis study reported in the Trifluralin Update was not included on the CSF. A nominal concentration must be included for this impurity. In addition, the nominal concentration listed for another impurity has been increased (approximately 10 fold) and is no longer representative of the preliminary analysis. The nominal concentration should be modified or an explanation of how this value was determined must be submitted. Additional data are required.

61-2. Description of Starting Materials and Manufacturing Process

I.Pi.Ci. has submitted (1994; MRID 43233001) supplemental information concerning the manufacturing process, and the suppliers and specifications of the starting materials for the 96% T. This information is presented in the Confidential Appendix. This information does

not satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding the starting materials and the production process for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3) because the registrant did not include the source for an intermediate which they stated may be purchased commercially rather than manufactured by I.Pi.Ci. Additional information is required.

61-3. Discussion of Formation of Impurities

I.Pi.Ci. has submitted (1994; MRID 43233001) a discussion of the formation of post-production impurities in the 96% T. The registrant maintains that no post-production contamination occurs in the 96% T. There is no possibility of contamination by other products because the plant only manufactures trifluralin and its intermediates. Equipment is dedicated to the production of trifluralin, and isocontainers or lined new drums are used for transfer and storage of the final product. The registrant states that the drum linings do not affect the nitrosamine content of the product even over long storage periods and at high temperatures. This additional information satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3). No additional information is required.

62-1. Preliminary Analysis

I.Pi.Ci. has provided (1994; MRID 43233001) supplemental information concerning the preliminary analysis data for seven samples of the 96% T. Refer to the Trifluralin Update for a complete discussion of the submitted data. In addition to the methods listed previously for the active ingredient and related impurities, I.Pi.Ci. has stated that a [redacted] These data satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3). No additional data are required.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

62-2. Certification of Limits

I.Pi.Ci. has submitted (1994; MRID 43233001) a CSF dated 3/4/94 for the 96% T. Data are presented in the Confidential Appendix. These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3) because an impurity detected at greater than 0.1% in the preliminary analysis study reported in the Trifluralin Update was not included on the CSF. An upper certified limit must be proposed for this impurity. In addition, the upper certified limit proposed for another impurity has been increased (approximately 10 fold) and is no longer representative of the preliminary analysis. The upper certified limit should be

modified or an explanation of how this value was determined must be submitted. Additional data are required.

62-3. Enforcement Analytical Methods

I.Pi.Ci. has submitted (1994; MRID 43233001) supplemental information in support of the analytical methods for determination of the active ingredient and related impurities of trifluralin which were described under Section 62-1, Preliminary Analysis, of the Trifluralin Update. New method validation was conducted because the original data could not be located. The registrant states that the linearity of the methods over various concentrations of trifluralin per se and related impurities was not checked because the levels of trifluralin and impurities present in the 96% T are standard. Representative chromatograms were included.

For GC/FID method AN/134/85, the trifluralin concentration determined by duplicate injections of five weighings of the 96% T ranged 96.37-97.03% with a mean of 96.69% ± 0.24. QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

[redacted]

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the I.Pi.Ci. 96% T (EPA Reg. No. 33660-3) because the concentration of a representative impurity in the standard solution mixture far exceeded the levels of the impurities it was intended to represent. If representative impurity standards are to be used for validation of the method then concentration ranges encompassing the typical impurity concentrations for which the standards are representative must be submitted. Additional data are required.

MASTER RECORD IDENTIFICATION NUMBERS

A citation for the MRID document referred to in this review is presented below.

43233001 I.Pi.Ci. Industria Prodotti Chimici SpA (1994) Trifluralin Technical - Product Chemistry Data Supplement to "Trifluralin Technical - Product Chemistry Data: Revised Product Identity," MRID No. 40743901, Data Requirement: Guideline Reference Nos. 61-1 through 61-3, Author I.Pi.Ci., Study Date: May 1988, and "Trifluralin Technical - Product Chemistry Data: Analysis and Certification of Product Ingredients" MRID No. 40743902, Data Requirement: Guideline Reference Nos. 62-1 through 62-3, Author I.Pi.Ci., Study Date: May 1988. I.Pi.Ci. study No. 976. Unpublished study submitted by I.Pi.Ci. Industria Prodotti Chimici SpA. 122 p.

Case No. 0179
Chemical No. 036101

Case Name: Trifluralin
Registrant: I.Pi.Ci.
Product(s): 96% T (EPA Reg. No. 33660-3)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number
61-1	Product Identity and Disclosure of Ingredients	N [b]	43233001
61-2	Starting Materials and Manufacturing Process	N [c]	43233001
61-3	Discussion of Formation of Impurities	Y	43233001
62-1	Preliminary Analysis	Y	43233001
62-2	Certification of Ingredient Limits	N [b]	43233001
62-3	Analytical Methods to Verify the Certified Limits	N [d]	43233001
63-2	Color	Y	
63-3	Physical State	Y	
63-4	Odor	Y	
63-5	Melting Point	Y	
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	
63-8	Solubility	Y	
63-9	Vapor Pressure	Y	
63-10	Dissociation Constant	Y	
63-11	Octanol/Water Partition Coefficient	Y	
63-12	pH	Y	
63-13	Stability	Y	
63-14	Oxidizing or Reducing Action	Y	
63-15	Flammability	N/A	
63-16	Explodability	Y	
63-17	Storage Stability	N	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	N	

[a] Y = Yes; N = No; N/A = Not Applicable. Data were submitted in response to the Trifluralin Reregistration Standard Update dated 10/29/91. Data requirements followed by MRID citations reflect conclusions determined in this document (D205239; CBRS No. 14012).

[b] An impurity detected at greater than 0.1% in the preliminary analysis study must be included on the CSF. A nominal concentration and upper certified limit must be proposed for this impurity. In addition, the nominal concentration and upper certified limit proposed for another impurity have been increased (approximately 10 fold) and are no longer

representative of the preliminary analysis. The nominal concentration and upper certified limit should be modified or an explanation of how these values were determined must be submitted.

[c] The source for an intermediate which may be purchased commercially rather than manufactured by I.Pi.Ci must be provided.

[d] If representative impurity standards are to be used for validation of the method then concentration ranges encompassing the typical impurity concentrations for which the standards are representative must be submitted.

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TRIFLURALIN (I.PI.CI.)

(CBRS No. 14012; DP Barcode D205239)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDIX

4 Page(s)

Confidential Appendix to the Scientific Review of a Registration Standard Followup Report for the pesticide trifluralin by the Chemistry Branch II Reregistration Support [Confidential FIFRA Trade Secret/CBI].

Page____ is not included in this copy.

Pages 10 through 14 are not included.

The material not included contains the following type of information:

___ Identity of product inert ingredients.

___ Identity of product impurities.

___ Description of the product manufacturing process.

___ Description of quality control procedures.

___ Identity of the source of product ingredients.

___ Sales or other commercial/financial information.

___ A draft product label.

___ The product confidential statement of formula.

___ Information about a pending registration action.

___ FIFRA registration data.

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

___ The document is not responsive to the request.

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