



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

APR 14 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Trifluralin Reregistration. Product Chemistry Data.

CBRS Nos.: 13148 and 13194

DP Barcode Nos.: D198774 and D198780

MRID Nos.: 43032201 and 42922501-42922506

Chemical No.: 036101

Reregistration Case No.: 0179

FROM: Bonnie Cropp-Kohlligian, Environmental Scientist
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Bonnie Cropp-Kohlligian

THRU: Paula A. Deschamp, Section Head
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Chemistry Branch II: Reregistration Support
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Paula A. Deschamp

TO: Lois Rossi/Walter Waldrop [PM 71]
Reregistration Branch
Special Review and Reregistration Division [7508W]

Attached is a review of the product chemistry data submitted by Agan Chemical Manufacturers, Ltd. in response to deficiencies identified in the Trifluralin Reregistration Standard Update pertaining to the Agan 98% T (EPA Reg. No. 11603-13). 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 (MRIDs 43032201 and 42922502-42922506) satisfy data



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requirements pertaining to the discussion of the formation of impurities, the dissociation constant, stability, oxidizing/reducing action, explosability, and corrosion characteristics of the 98% T (Guideline Reference Numbers 61-3, 63-10, 63-13, 63-14, 63-16, and 63-20, respectively). The submitted data (MRID 42922501) do not satisfy data requirements pertaining to enforcement analytical methods (Guideline Reference Number 62-3) because validation data were not submitted for three impurities.

If you need addition input please advise.

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

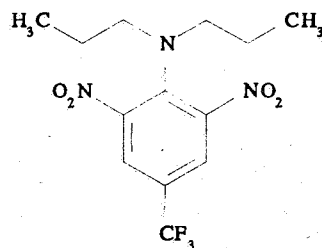
cc (with Attachment 1 and 2): BLCKohlligian (CBRS), Trifluralin Registration Standard File, Trifluralin Update File, Trifluralin SF, Dynamac.

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

RDI: PDeschamp:4/14/94 MMetzger:4/14/94 EZager:4/14/94

7509C:CBRS:BLCKohlligian:CM#2:Rm 805B:703-305-7462:4/11/94.

TRIFLURALIN



Shaughnessy No. 036101; Case 0179

(CBRS Nos. 13148 and 13194; DP Barcodes D198774 and D198780)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to the Trifluralin Reregistration Standard Update dated 10/29/91, Agan Chemical Manufacturers, Ltd. has submitted seven volumes of product chemistry data (MRIDs 42922501 through 42922506, and 43032201) for the 98% technical (T; EPA Reg. No. 11603-13). The submitted data and our conclusions are discussed below.

61-3. Discussion of Formation of Impurities

Agan has submitted (1993; MRID 43032201) a discussion of the formation of post-production impurities in the 98% T. No post-production impurities are expected to form in the 98% T; stability studies demonstrate that the technical (active ingredient) is stable for at least two years, and no nitrosating agents are present in the product or in the packaging. Technical trifluralin is stored/shipped in drums with a phenol-epoxy coating. The coating is baked onto the drum at 200°C, leaving a non-porous, inert finish. This information satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the Agan 98% T (EPA Reg. No. 11603-13). No additional information is required.

62-3. Enforcement Analytical Methods

Agan has submitted (1993; MRID 42922501) validation data for the analytical methods presented under CBRS Nos. 7175, 7176, and 7177, dated 3/5/91, by R. Perfetti. Adequate linearity, accuracy, and precision data were submitted in support of the GC/FID method used for the determination of the active ingredient. The validation data submitted in support of the method for the determination of the impurities of trifluralin are discussed in the Confidential Appendix.

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the Agan 98% T (EPA Reg. No. 11603-13) because validation data were not submitted for three impurities related to the active ingredient and listed on the CSF with proposed upper certified limits. In addition, only partial validation data were submitted for the impurities discussed; precision coefficients determined from replicate injections must be submitted. Additional data are required.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Agan submitted (1993; MRIDs 42922502 through 42922506) data concerning the dissociation constant, stability, oxidizing/reducing action, explodability, and corrosion characteristics of the 98% T. These properties are presented in Table 1. In addition, the registrant included a study protocol for a one-year storage stability study of the 98% T stored under warehouse conditions in the typical commercial packaging (12-month sampling is tentatively scheduled to occur 9/94). The submitted data satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-10, -13, -14, -16, and -20) for the Agan 98% T (EPA Reg. No. 11603-13); however, data pertaining to storage stability (Guideline Reference No. 63-17) remain outstanding.

Table 1. Physical and chemical properties of the Agan 98% T (EPA Reg. No. 11603-13).

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method; MRID]
63-10.	Dissociation constant	estimated pK_a ranging 1 to 2; a spectrum could not be isolated for the fully ionized or molecular species [UV-VIS spectrophotometer; 42922502]
63-13.	Stability	stable physically and chemically upon exposure to: elevated temperatures (54°C) for 14 days, iron chips at 25°C for 24 hours, and sunlight for 24 hours [GC/FID; 42922503]
63-14.	Oxidizing/ reducing action*	does not demonstrate any oxidizing or reducing action when placed in contact with water, monoammonium phosphate, iron, or a dilute neutral solution of potassium permanganate for 24 hours [44 FR 16267 (3/16/79); 42922504]
63-16.	Explodability	slightly sensitive toward impact initiation (50% initiation height of 33.5 ± 0.5 inches) [Drop Weight JANNAF Test, ASTM E.680-79; 42922505]
63-20.	Corrosion characteristics	no corrosion of coupons (coated with the typical drum lining used for storage) exposed to the product for 7 days [ASTM G31-72; 42922506]

AGENCY MEMORANDUM CITED

CBRS No(s): 7175, 7176, and 7177
Title: Response to the Trifluralin Reregistration Standard: Product Chemistry Data.
From: R. Perfetti
To: R. Engler and L. Rossi
Dated: 3/5/91
MRID(s): 40454701

MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID documents referred to in this review are presented below.

42922501 Agan Chemical Manufacturers, Ltd. (1993) Triflurex Technical - Validation of Analytical Method for Active Ingredient and Evaluation of Validity for the Calculation of Impurity Levels; Supplement to MRID 40454701. Laboratory Project ID: 9-08A. Unpublished study prepared by Agan Chemical Manufacturers, Ltd. 39 p.

42922502 Rondon, C. and Stashick, J. (1993) Dissociation Constant(s) of Triflurex Technical. Laboratory Project ID: 93-6407-24. Unpublished study prepared by ARCTECH, Inc. and submitted by Agan Chemical Manufacturers, Ltd. 28 p.

42922503 Rondon, C. and Stashick, J. (1993) Stability of Triflurex Technical. Laboratory Project ID: 93-6407-25. Unpublished study prepared by ARCTECH, Inc. and submitted by Agan Chemical Manufacturers, Ltd. 47 p.

42922504 Rondon, C. (1993) Oxidizing or Reducing Action of Triflurex Technical. Laboratory Project ID: 93-6407-28. Unpublished study prepared by ARCTECH, Inc. and submitted by Agan Chemical Manufacturers, Ltd. 26 p.

42922505 Rondon, C. (1993) Explodability of Triflurex Technical. Laboratory Project ID: 93-6407-26. Unpublished study prepared by ARCTECH, Inc. and submitted by Agan Chemical Manufacturers, Ltd. 29 p.

42922506 Rondon, C.; Stashick, J. (1993) Corrosion Characteristics of Triflurex Technical. Laboratory Project ID: 93-6407-27. Unpublished study prepared by ARCTECH, Inc. and submitted by Agan Chemical Manufacturers, Ltd. 34 p.

43032201 Agan Chemical Manufacturers, Ltd. (1993) Triflurex Technical (trifluralin) Post-Production Discussion. Unpublished study prepared by Agan Chemical Manufacturers, Ltd. 4 p.

Case No. 0179
Chemical No. 036101

Case Name: Trifluralin
Registrant: Agan Chemical Manufacturers, Ltd.
Product(s): 98% T (EPA Reg. No. 11603-13)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number
61-1	Product Identity and Disclosure of Ingredients	Y	
61-2	Starting Materials and Manufacturing Process	Y	
61-3	Discussion of Formation of Impurities	Y	43032201
62-1	Preliminary Analysis	N ^b	
62-2	Certification of Ingredient Limits	N ^c	
62-3	Analytical Methods to Verify the Certified Limits	N ^d	42922501
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	42922502
63-11	Octanol/Water Partition Coefficient	Y	
63-12	pH	Y	
63-13	Stability	Y	42922503
63-14	Oxidizing or Reducing Action	Y	42922504
63-15	Flammability	N/A	
63-16	Explosibility	Y	42922505
63-17	Storage Stability	N	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	Y	42922506

^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 (CBRS No. 13148).

^b Nitrosamine analysis must be conducted on samples from one representative batch of the product collected immediately after production, three months after production, and six months after production.

^c The upper certified limit for an impurity must be revised because the nominal concentration exceeds the proposed upper limit. Certifications must be resubmitted on EPA Form 8570-4 (Rev. 12/90).

^d Complete validation data must be submitted for three impurities related to the active ingredient and listed on the CSF with proposed upper certified limits. In addition, precision coefficients determined from replicate injections must be submitted for the impurities for which partial validation have been received.

CONFIDENTIAL

TRIFLURALIN (AGAN; CBRS No. 13194; DP Barcode No. D198780)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDIX

1 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 10 is not included in this copy.

Pages _____ through _____ 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.
