Rec'd S. Gowanlock 6/28/91

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

JUN 27 1991

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

Subject: Product Chemistry Review on Barricade® T Herbicide

EPA File Symbol: 55947-UR

From: Radamés Lozada, Chemist
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

To: Joanne I. Miller, PM 23
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Alfred Smith for:
Bipin Gandhi, Section Head
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

Requestor: Sandoz Crop Protection Corporation

EPA File Symbol: 55947-UR

EPA MRID No.: 417688-01 through 417688-19

Pesticide Chemical Code: 110201-1

Company Code No.: SAN 745H

Chemical Name: N3, N^3-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine

Common\Trade Name: Prodiamine\Barricade®

Use: herbicide

Printed on Recycled Paper

Introduction:

This submission (from Sandoz Crop Protection Corporation dated February 1,1991) is for Barricade® T Herbicide (referred to as Technical Prodiamine in previous submissions) which contains the active ingredient N^3, N^3-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine.

The registrant has submitted a new set of data that is more accurate and up-to-date information for the TGAI. Therefore this review will address all the submitted data, including those requirements that were found adequate in previous reviews. The purpose of doing this is to have a review that summarizes the most recent data.

The product chemistry data for Technical Prodiamine and two EPs was previously reviewed by Radamés Lozada of Registration Support Branch, Registration Division on July 24, 1990. The following deficiencies were found for Technical Prodiamine:

SERIES 61: Product Identity and Composition

1. A new CSF for the TGAI with the CAS numbers for all the impurities that are required to be listed on it. Also the registrant must include the amount and the percent by weight for each component in the formulation.

2. The label of the technical should have the nominal concentration.

SERIES 62: Analysis and Certification of Product Ingredients

1. A new preliminary analysis is still required in order to satisfy the requirements of § 62-1 of the Pesticide Assessment Guidelines-Product Chemistry-Subdivision D. Also, copies of the spectral data of the analyses must be submitted.If new impurities are found in this analyses then the new CSF should be revised accordingly.

SERIES 63: Physical and Chemical Characteristics

1. The solubility of the TGAI in octanol shall be determined at 20°C or 25°C as required under § 63-8.

All product chemistry data requirements pertaining to the TGAI as described in 40 CFR Subpart C § 158.150 - 158.190 must be satisfied to achieve full registration.

This review will address the submitted data for the TGAI as it relates to the product chemistry data requirements. The data submitted for the two EPs will be reviewed separately in accordance with new procedures of Product Chemistry Review Section.

SERIES 61: Product Identity and Composition

61-1 Product Identity and Disclosure of Ingredients

The submitted CSF (dated March 22, 1991) and the new label reflecting 93% of active ingredient (AI) for Barricade® T Herbicide are complete and acceptable. No further information is required for this topic.

61-2 Description of Beginning Materials and Manufacturing Process

The registrant has submitted a modified manufacturing process for the TGAI. The modification consists of [redacted] Current information of the beginning materials was also submitted. Refer to Confidential Appendix A for a description of the beginning materials and manufacturing process for the TGAI. No further information is required for this topic.

61-3 Discussion of the Formation of Impurities

Refer to Confidential Appendix A for a detailed discussion of the formation of impurities for technical prodiamine.

The registrant has submitted additional analytical data (MRID NO. 417688-02, pages 155-185) that shows that nitrosamines concentration in the TGAI is not greater than 0.5 ppm. The actual policy on nitrosamines (45 FR 42854) requires that pesticide products containing dinitroanilines (which is the case) must be analyzed to verify that they contain less than 1 ppm of nitrosamines. Therefore, the registrant has met this requirement for the TGAI.

No further information is required for this topic.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

SERIES 62: Analysis and Certification of Product Ingredients

62-1 Preliminary Analysis of Product Samples

The registrant has submitted the results of analyses of five representative samples of the technical material which were analyzed for the AI and the impurities to support the modifications on the manufacturing process. Refer to Confidential Appendix B for the results of these analyses. No further information is required for this topic.

62-2 Certification of Ingredient Limits

The registrant has submitted a CSF which includes the certified limits for the AI and the impurities present in Barricade® T Herbicide. Refer to Confidential Appendix B for a disclosure of these limits. No further information is required for this topic.

62-3 Analytical Methods to Verify Certified Limits

The registrant has submitted analytical methods and spectral data to verify the certified limits of the AI and the impurities present in Barricade® T Herbicide. The AI and impurities content were determined by gas chromatography with a flame ionization detector at various chromatographic conditions. These methods and the spectroscopic data can be found in MRID NO. 417688-02 pages 37 through 154. All analytical methods were validated with respect to linearity, precision, and accuracy. No further information is required for this topic.

SERIES 63: Physical and Chemical Characteristics

Summarized below are several physicochemical properties of the TGAI as furnished by the applicant. All properties were supported by reports that described the laboratory protocols, results and validation of the procedures taken to measure them. These reports can be found in MRID Nos. 417688-04 through 417688-19. These requirements are adequately fulfilled for the technical material.

Guidelines Reference No. (40 CFR 158.190) and Name of Property	TGAI
63-2 Color	yellow-orange
63-3 Physical State	powdered solid
63-4 Odor	halide odor

Guidelines Reference No. (40 CFR 158.190) and Name of Property	TGAI
63-5 Melting Point	122.5 - 124.0°C
63-6 Boiling Point	N.A.
63-7 Density	1.4107 g/ml
63-8 Solubility	
water	13 ppb @ 25°C
acetone	22.600 g/100ml @25°C
n-octanol	0.962 g/100ml @ 25°C
dimethylformamide	32.100 g/100ml @ 20°C
xylene	3.540 g/100ml @ 20°C
isopropanol	0.852 g/100ml @ 20°C
heptane	0.100 g/100ml @ 20°C
63-9 Vapor Pressure	2.5×10^{-8}
63-10 Dissociation Constant[1]	$pK_a = 11.5$ $K_a = 3.16 \times 10^{-12}$
63-11 Octanol/ Water Partition Coefficient	1.3×10^4
63-12 pH	6.878 @ 25°C
63-13 Stability	Thermally stable. Moderately stable to light. Decompose at 240°C.[2]
63-14 Oxidizing or Reducing Action	slight oxidizing potential.
63-15 Flammability	N.R.
63-16 Explodability	non-explosive

[1] As reported in the first submission.

[2] The Agrochemicals Handbook, 2nd edition.

Guidelines Reference No. (40 CFR 158.190) and Name of Property	TGAI
63-17 Storage Stability	Stable for: 84 days @ 54°C 168 days @ 40°C 1 year @ ambient temperature
63-18 Viscosity	N.R.
63-19 Miscibility	N.R.
63-20 Corrosion Characteristics	No expected reactivity towards the packaging material.
63-21 Dielectric Breakdown Voltage	N.R.

N.A. means not applicable.
N.R. means not required.

Conclusions and Recommendations

The product chemistry data requirements for Barricade® T Herbicide have been completely satisfied. Therefore no additional data are required.

Note to the PM: Prodiamine is a dinitroaniline; therefore, the end-use product must be analyzed for nitrosamine contaminants at the time of commercial production. The nitrosamine sampling requirements appear in Appendix A of the 6-25-80 Federal Register Notice (45 FR 42854).

Attachments:

Confidential Appendix A
Confidential Appendix B

110201
~~112020~~ PRODIAMINE PIN 1786-95

Page_____ is not included in this copy.

Pages 7 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.