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

FEB 15 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

Subject: Product Chemistry Review on Technical Prodiamine and the end products Prodiamine 65WDG and Endurance 65WDG
EPA File Symbol: 55947-UR, 55947-UE, 55947-UG

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Thru: Lynn M. Bradley, Head
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Requestor: Sandoz Crop Protection Corporation

EPA File Symbol: 55947-UR, 55947-UE, 55947-UG

EPA MRID No.: 402293-01C, 02C
405934-01, 02, 03

Company Code No.: CN-11-2936, USB-3153 (technical)

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

Pesticide Chemical Code: 110201-1

Common/Trade Name: prodiamine

Use: herbicide

Introduction:

This submission (from Sandoz Crop Protection Corporation dated February 21, 1989) is for Technical Prodiamine and two EPs (Prodiamine 65WDG, Endurance 65WDG) which contain the active ingredient N^3, N^3-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine. All product chemistry data requirements pertaining to the TGAI and the EPs as described in the 40 CFR 158.120 must be satisfied to achieve full registration. The product chemistry data for Prodiamine Technical and both EPs was previously reviewed by Francis B. Suhre of Residue Chemistry Branch, Hazard Evaluation Division on November 21, 1986. The following deficiencies were found for the TGAI and the EPs:

1. § 61-1: The Confidential Statement of Formula (CSF) for Prodiamine 65WDG, Endurance 65WDG and Prodiamine technical were submitted on EPA Form 8570-4 (revised 10-81). The registrant must resubmit the CSFs for each product on EPA Form 8570-4 (revised 2-85). The 2-85 revised form requires that a certified upper and lower limit be provided for the active ingredient and that a certified upper limit be provided for all other components. This information was not required on the earlier form.

2. § 61-2: The registrant has not adequately described the manufacturing process for technical Prodiamine.

3. § 61-3: Prodiamine is a dinitroaniline; therefore, the technical product must be analyzed for nitrosamine contaminants. The registrant has provided nitrosamine data on laboratory and pilot plant production runs of Prodiamine. The data indicates that the levels of nitrosamine in the technical product can be controlled (kept below 1.0 ppm) by adjusting the manufacturing process. At the time of commercial production (technical prodiamine) the registrant must analyze samples, from at least 5 production runs, for the presence of nitrosamine contaminants. The nitrosamine sampling requirements appear in Appendix A of the 6-25-80 Federal Register Notice; 42854 FR No. 125.

4. § 62-1: The data submitted for the preliminary analysis of technical Prodiamine is not adequate to support registration. The registrant must analyze 5 or more representative samples and must submit the data for each sample. In addition, the registrant must chemically elucidate the structure of each impurity present at >0.1 % in the technical product.

5. § 64-1: The registrant should submit samples of analytical grade and technical grade Prodiamine to BUD, OPTS, USEPA at Beltsville, MD., if they have not already done so.

SERIES 61: Product Identity and Composition

The submitted CSF for Prodiamine 65WDG is acceptable and the intentionally added inert ingredients found in this formulation have been approved by the Agency for use in non-food use pesticide formulations.

The registrant must submit a CSF for the technical product and Endurance 65WDG on EPA form 8570-4 (revised 2-85). This form requires that the certified upper limit be provided for each impurity at a level greater than or equal to 0.1 % for the technical product.

The submitted manufacturing process is still not acceptable. The following information is needed in order to fulfill the requirements of this topic: a detailed description of the equipment used to produce the product (TGAI) which may influence the product's composition; a description of measures taken to assure the quality of the final product, including procedures involving the equipment used for blending product components and for filling and packaging.

SERIES 62: Analysis and Certification of Product Ingredients

The applicant has submitted the results of analyses of five representative samples of the technical product which were analyzed for the AI and [redacted] impurities. These analyses are not acceptable until each impurity present at levels $\geq$ 0.1% is identified and declared on the CSF. Refer to Confidential Appendix A for the results of these analyses. This information was taken directly from the submission.

Refer to Confidential Appendix A for a disclosure of the new elucidation of the impurities and the certification limits on the TGAI submitted by the registrant. This information was taken directly from the submission. These new certification limits still must be presented in the proper form (EPA Form 8570-4, revised 2-85) in order to be acceptable for registration.

The registrant must explain the broad difference between the lower and upper certified limits of the active ingredient in the technical product.

SERIES 63: Physical and Chemical Characteristics

Based on recent test results, the following physical and chemical characteristics have been revised for Prodiamine 65WDG:

§ 63-8	Solubility	water, 0.013 ppm at 25°C
§ 63-9	Vapor pressure	2.51×10^{-8} mmHg at 25°C
§ 63-11	Octanol/water partition coefficient	12,672 ± 2,270 at 25°C

Conclusions and Recommendations:

After reviewing the information submitted by Sandoz in response to the letter send by EPA on December 4, 1986 the reviewer has found that information is still needed in each one of the previously noted deficiencies.

The product chemistry data requirements for the TGAI and both EPs have not been completely satisfied. The following information is still required.

SERIES 61: Product Identity and Composition

1. The registrant must submit a CSF for the technical product and Endurance 65 WDG on EPA form 8570-4 (revised 2-85). This form requires that the certified upper limit be provided for each impurity at a level greater than or equal to 0.1 % for the technical product.

2. A detailed description of the equipment used to produce the product (TGAI) which may influence the product's composition.

3. A description of measures taken to assure the quality of the final product, including procedures involving the equipment used for blending product components and for filling and packaging.

SERIES 62: Analysis and Certification of Product Ingredients

1. The data submitted for the preliminary analysis of the technical product is still not adequate to support registration. The registrant must chemically identify and elucidate the structure of each impurity present at levels $\geq$ 0.1% in the technical product.

2. The registrant must explain the broad difference between the lower and upper certified limits of the active ingredient in the technical product.

SERIES 63: Physical and Chemical Characteristics

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

Note to the PM: Prodiamine is a dinitroaniline; therefore, the ~~technical~~ 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 A

TABLE 1

MATERIAL BALANCE OF TECHNICAL PRODIAMINE

COMPONENT	LOT # C-86226	LOT # C-86253	LOT # C-86265	LOT # C-86273	LOT # C-86277
PRODIAMINE	91.21	94.55	92.80	90.54	93.91
I	0.14	0.06	0.10	0.02	0.15
J	0.17	0.21	0.12	0.18	0.24
J'	0.10	0.09	0.10	0.09	0.08
K	0.01	N.D.	N.D.	0.003	0.01
L	0.61	0.58	0.40	0.45	0.61
N'	N.D.	N.D.	0.01	<0.02	<0.02
O	6.25	3.72	6.19	7.24	4.40
TOTAL	98.51	99.21	99.71	98.52	99.40

N.D. = Not Detected

Where:

Prodiamine = N^3,N^3-Di-n-propyl-2,4-dinitro-6-trifluoromethyl-m-phenylenediamine.

I = 2,3-Dichloro-6-nitro-4-trifluoromethylaniline.

J = N,N-Di-n-propyl-2,3-dichloro-6-nitro-4-trifluoromethylaniline.

J' = N,N-Di-n-propyl-2,6-dinitro-4-trifluoromethylaniline.

K = N,N-Di-n-propyl-5-chloro-2-nitro-4-trifluoromethylaniline.

L = N,N-Di-n-propyl-3-chloro-2,6-dinitro-4-trifluoromethylaniline.

N' = N^1,N^1,N^3,N^3-Tetra-n-propyl-2,4-dinitro-6-trifluoromethyl-m-phenylenediamine.

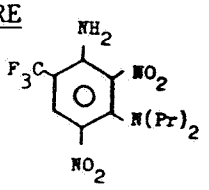
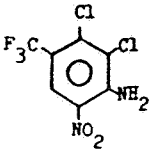
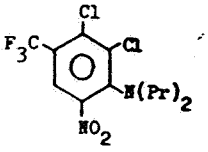
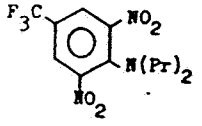
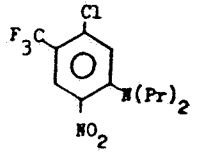
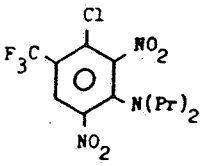
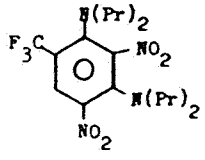
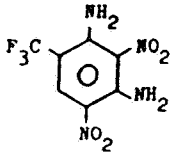
O = 2,4-Dinitro-6-trifluoromethyl-m-phenylenediamine.

taken from submission

Preliminary Analysis - Supplemental Data to Sandoz
Report No. 480423-2, EPA MRID No. 40229302

TABLE 2

CHEMICAL STRUCTURES

STRUCTURE	COMPONENT
	prodiamine = N^3,N^3-Di-n-propyl-2,4-dinitro-6-trifluoromethyl-m-phenylenediamine
	(I) = 2,3-Dichloro-6-nitro-4-trifluoromethylaniline
	(J) = N,N-Di-n-propyl-2,3-dichloro-6-nitro-4-trifluoromethylaniline
	(J^1) = N,N-Di-n-propyl-2,6-dinitro-4-trifluoromethylaniline
	(K) = N,N-Di-n-propyl-5-chloro-2-nitro-4-trifluoromethylaniline
	(L) = N,N,-Di-n-propyl-3-chloro-2,6-dinitro-4-trifluoromethylaniline
	(N^1) = N^1,N^1,N^3,N^3-Tetra-n-propyl-2,4-dinitro-6-trifluoromethyl-m-phenylenediamine
	(O) = 2,4-Dinitro-6-trifluoromethyl-m-phenylenediamine

PRODIAMINE TECHNICAL
CERTIFICATION OF LIMITS
GUIDELINES NO. 62-2

(Supercedes EPA Accession No. 256457)

CONSTITUENT	LOWER LIMIT*	UPPER LIMIT*
Prodiamine	90.0	100.0
I	0	0.3
J	0	0.4
J^1	0	0.2
K	0	0.03
L	0	0.9
N^1	0	0.03
O	0	10.0

*Wt. % limits

Where:

Prodiamine = N^3,N^3-Di-n-propyl-2,4-dinitro-6-trifluoromethyl-m-phenylenediamine.

I = 2,3-Dichloro-6-nitro-4-trifluoromethylaniline.

J = N,N-Di-n-propyl-2,3-dichloro-6-nitro-4-trifluoromethylaniline.

J' = N,N-Di-n-propyl-2,6-dinitro-4-trifluoromethylaniline.

K = N,N-Di-n-propyl-5-chloro-2-nitro-4-trifluoromethylaniline.

L = N,N-Di-n-propyl-3-chloro-2,6-dinitro-4-trifluoromethylaniline.

N^1 = N^1,N^1,N^3,N^3-Tetra-n-propyl-2,4-dinitro-6-trifluoromethyl-m-phenylenediamine.

O = 2,4-Dinitro-6-trifluoromethyl-m-phenylenediamine.

Taken from submission