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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

Subject: Product Chemistry Review on Technical
Prodiamine and Prodiamine 65WDG
(end-use product).
EPA File Symbol: 55947-UR, 55947-UG

From: Radamés Lozada, Chemist
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Registration Division (H7505C)

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

Thru: Donald Stubbs, Acting Section Head
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

Requestor: Sandoz Crop Protection Corporation

EPA File Symbol: 55947-UR, 55947-UG

EPA MRID No.: 414067-01

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

Chemical Name: N³, N³-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 March 5, 1990.) is for Technical Prodiamine and the Prodiamine 65WDG (EP) which contain the active ingredient N³, N³-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine. All product chemistry data requirements pertaining to the TGAI and the EP as described in the 40 CFR 158.120 must be satisfied to achieve full registration. The product chemistry data for Prodiamine Technical and two EPs was previously reviewed by Radamés Lozada of Registration Support Branch, Registration Division on February 15, 1990. The following deficiencies were found for the TGAI and the EPs:

1. Series 61:

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

2. Series 62:

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

3. Series 63:

- a. 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.

SERIES 61: Product Identity and Composition

The CSF for the TGAI is still incomplete. CAS numbers for all the impurities has not been assigned. To obtain those numbers the registrant should contact CAS Registry Services at the following address:

CAS Registry Services
P.O. Box 3343
Columbus, OH
43210

Also the registrant must includes the amount and the % by weight for each component in formulation. That information was not provided in the last submitted CSF (dated March 2, 1990). Refer to Confidential Appendix B for a disclosure of the CSF.

Endurance 65 WDG herbicide (55947-UE) application has being withdrawn. Therefore, the required data for this product have not being submitted.

Refer to Confidential Appendix A for a description of the equipment used to produce the technical product and a description of the measures taken to assure the quality of the final product. No additional information is required for this topic.

The label of the technical should have the nominal concentration which is 93% (according to the new CSF). The registrant must be aware that a change in the nominal concentration of the technical will have an impact on the nominal concentration of the EP.

Upon reevaluation we have discovered that the following data have never been submitted for Prodiamine 65 WDG, as required for end-use products:

1. A complete description of the manufacturing/formulation process.
2. A description of impurities formed during the formulation process, in packaging, or during storage. If no impurities are expected to form during these stages, please so state.

Therefore data are needed to address these deficiencies.

SERIES 62: Analysis and Certification of Product Ingredients

In response to the required information pointed out in the last review, the registrant has made the following statement (submittal letter dated March 2, 1990):

"A new 5 batch analysis report was submitted May 26, 1987 and assigned MRID# 4022932-02. The structures were inadvertently omitted from this report. Consequently, a supplemental submission was made April 14, 1988 with these structures and assigned MRID# 405934-02. The new batch analysis was based on product produced under the process also submitted May 26, 1987 and updated April 14, 1988. This analysis, included in this review, indicated [redacted] total impurities $\geq 0.1\%$ (MRID# 402293-02 and 405934-02). This was substantially lower than the [redacted] impurities present in the original process material [redacted] of which were completely identified and [redacted] of which were not). The certification of limits was amended accordingly indicating the presence of [redacted] impurities, all of which were identified in MRID# 405934-02. All other impurities are present at $< 0.1\%$ and do not require complete identification."

The previous review (dated February 15, 1990) addressed such data, as it shows on the first page. The data reviewed was the one contained on MRIDs 402293-01, -02 and 405934-01, -02, -03. The reasons why a new preliminary analysis was required were the following: the fact that the sums of the analyses do not add up to an average of 100% suggest that some impurities have not been identified; furthermore in the first analysis submitted by the registrant (Accession # 260677) there were [redacted] impurities with levels $\geq 0.1\%$ and with no changes in the manufacturing process, since then, is not clear why they don't show up in the new analysis. Therefore 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 these analyses then the new CSF should be revised accordingly.

New limits are proposed on the CSF of Prodiamine Technical for the AI. Refer to Confidential Appendix B for a disclosure of these limits. We are unable to reach a final conclusion about the proposed certified limits until a new preliminary analysis is submitted.

PRODUCT IMPURITY INFORMATION NOT INCLUDED

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SERIES 63: Physical and Chemical Characteristics

In the previous review (dated February 15, 1990.) the following physicochemical properties were listed under the formulation product (Prodiamine 65WDG) as is state on the MRID # 405934-03, page 4. Now the registrant said that those properties belong to the technical product (submittal letter dated March 2, 1990.).

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

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

Upon reevaluation we have discovered that the following physicochemical properties have never been submitted for Prodiamine 65 WDG as required for end-use products.

- 63-2 Color
- 63-3 Physical State
- 63-4 Odor
- 63-7 Density
- 63-12 pH
- 63-14 Oxidizing or Reducing Action
- 63-15 Flammability
- 63-16 Explodability
- 63-17 Storage Stability
- 63-18 Viscosity
- 63-19 Miscibility
- 63-20 Corrosion Characteristic
- 63-21 Dielectric Breakdown Voltage

Therefore, data are needed to address these deficiencies.

Conclusions and Recommendations:

After reviewing the information submitted by Sandoz in response to the letter send by EPA on February 22, 1990 the reviewer has found that information is still needed in some of the previously noted deficiencies.

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

SERIES 61: Product Identity and Composition

Technical Prodiamine :

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 % by weight for each component in formulation.
2. The label of the technical should have the nominal concentration which is 93% (according to the new CSF).

Prodiamine 65WDG Herbicide:

1. A complete description of the manufacturing/formulation process.
2. A description of impurities formed during the formulation process, in packaging, or during storage. If no impurities are expected to form during these stages, please so state.

SERIES 62: Analysis and Certification of Product Ingredients

Technical Prodiamine :

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

Technical Prodiamine :

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

Prodiamine 65WDG Herbicide:

1. Data reflecting the following physicochemical properties for the EP:
 - 63-2 Color
 - 63-3 Physical State
 - 63-4 Odor
 - 63-7 Density
 - 63-12 pH
 - 63-14 Oxidizing or Reducing Action
 - 63-15 Flammability
 - 63-16 Explodability
 - 63-17 Storage Stability
 - 63-18 Viscosity
 - 63-19 Miscibility
 - 63-20 Corrosion Characteristic
 - 63-21 Dielectric Breakdown Voltage

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

PRODIAMINE

FIN 1786-93

Page is not included in this copy.

Pages 8 through 11 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.
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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.
