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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: 55947-UR,-UE,-UG. Prodiamine: Product Chemistry Data; Accession Numbers 263735, 263736, 263737, 260677, 256457, and 253052; RCB Numbers 1215, 1216, and 1217.

From: Francis B. Suhre, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: for Edward Zager, Section Head
Special Registration Section II
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To: R. Mountfort, PM-23
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Registration Division (TS-767)

Sandoz Crop Protection Corp.(Velsicol Chemical), Chicago, Illinois, has requested registration for Endurance 65WDG Herbicide and Prodiamine 65WDG Herbicide. Prodiamine, the TGAI in both products, is a new pesticide chemical.

Endurance 65WDG and Prodiamine 65WDG are chemically identical; they contain 65% Prodiamine [N^3,N^3-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine] as their active ingredient.

Technical grade Prodiamine contains 90% N^3,N^3-Di-n-propyl-2,4-dinitro-6(trifluoromethyl)-m-phenylenediamine and 10% related compounds.

Endurance 65WDG is intended for use in non-bearing orchards of fruit, nut, and vine crops. The label includes the following use restriction: Do not apply to crops that will produce a harvestable crop within one year after application. An Experimental Use Permit for this use was granted in 1985 (876-EUP-44). Prodiamine 65WDG is intended for use on turf and ornamentals only. Both products are intended for non-food use.

Temporary tolerances were established for Prodiamine residues in a number of raw agricultural commodities in support of experimental use permits. Peviously issued temporary tolerances are listed below:

Crop	Temporary Tolerance	Date Expired
Almond hulls	0.1 ppm	4-21-78
Cottonseed	0.1 ppm	4-21-78
Cottonseed forage	0.1 ppm	4-21-78
Grapes	0.1 ppm	4-21-78
Nuts	0.1 ppm	4-21-78
Soybeans	0.1 ppm	10-2-80
Soybeans, hay and forage	0.1 ppm	10-2-80
Stone fruit	0.1 ppm	10-2-80

Petition PP9#F2236, for the permanent tolerances listed below, is currently in reject status (A. Smith, memorandum of 9-16-80).

Crop	Permanent Tolerance	Date Petition submitted
Almond hulls	0.1 ppm	9-13-79
Almonds	0.1 ppm	9-13-79
Cottonseed	0.1 ppm	9-13-79
Cottonseed forage	0.1 ppm	9-13-79
Grapes	0.1 ppm	9-13-79
Soybeans	0.1 ppm	9-13-79
Soybean, hay and forage	0.1 ppm	9-13-79
Walnuts	0.1 ppm	9-13-79

The registrant has provided product chemistry data intended to fulfill the product chemistry requirements for registration of two End Use Products (EPs), Endurance 65WDG and Prodiamine 65WDG, as well as registration of the Technical Grade Active Ingredient (TGAI), Prodiamine, used in both of these products. RCB will only address the product chemistry requirements for technical prodiamine.

Product Chemistry Data Requirements (40 CFR 158.120)

Guideline reference:

§ 61-1: Product identity and disclosure of ingredients

The registrant is required to provide the name, nominal concentration, and certified limits of each active ingredient and the name, nominal concentration, and upper limit of each impurity. For each active, the information should include the molecular, empirical, or structural formulas; the CAS number; and molecular weight.

Data submitted in response to the requirements of § 61-1 is given and discussed in the Confidential Appendix to this review.

§ 61-2: Description of the beginning materials and manufacturing process and 61-3: Discussion of formation of impurities.

The registrant is required to provide the identity of the suppliers of the beginning materials and to provide a full descriptions of the beginning materials. The description of the manufacturing process should include a discussion of each individual reaction in the process, the relative amounts of the reacting materials, the physical conditions of each step, and any purification procedures. A discussion is required to account for the presence of potential or actual impurities based upon knowledge of the composition of beginning materials, desired and side reactions of the manufacturing process, and contamination or degradation of the active material.

Data submitted in response to the requirements of § 61-2 and § 61-3 are given and discussed in the Confidential Appendix to this review.

§ 62-1: Preliminary analysis; § 62-2: Certification of limits and § 62-3: Analytical methods to verify certified limits.

The registrant is required to provide compositional data (based on a preliminary analysis of the product) to support the registration of each manufacturing-use product and those end-use products produced by an integrated formulation system. If the technical chemical has not been used as a formulating ingredient in registered products, the preliminary analysis will include technical chemical (TGAI).

Data submitted in response to the requirements of § 62-1 and § 62-3 are given and discussed in the Confidential Appendix to this review.

§ 63-2 through 63-21: Physical and Chemical Characteristics.

The physical and chemical characteristics of EPs and non-registered TGAIs must be summarized and the methods used to obtain those characteristics must also be referenced or described.

Physical and chemical characteristics for the non-registered TGAI, Prodiamine, were provided as follows:

Physical and Chemical Characteristics of Prodiamine (TGAI)

§ 63-2	Color:	Dark yellow
§ 63-3	Physical State:	Crystalline solid powder
§ 63-4	Odor:	None
§ 63-5	Melting point:	124°-125°C
§ 63-7	Specific gravity	1.47
§ 63-8	Solubility:	Water 0.05 ppm at 25°C

Organic Solvent (20°C) Solubility, Wt. %

Tetrahydrofuran	32.6
Dimethylformamide	30.4
Dimethylsulfoxide	21.5
Acetone	20.5
Isophorone	17.0
Methyl Isoamyl Ketone	11.8
Diglyme	11.3
Amyl Acetate	10.5
Chloroform	9.3
Benzene	7.4
Acetonitrile	4.5
Xylene	3.7
Cyclohexane	1.4
Ethanol	0.7

§ 63-9	Vapor pressure	2.5×10^{-7} mm Hg at 25°C
§ 63-10	Dissociation constant	pKa = 11.5 Ka = 3.16×10^{-12}

§ 63-11	Octanol/water partition coefficient	3.3×10^4
§ 63-12	pH:	pH was not effected when dispersed in water
§ 63-13	Stability:	Prodiamine appears to be stable under thermal and hydrolytic conditions. Under laboratory photolysis conditions prodiamine rapidly degrades. This is also the case when aqueous solutions are exposed to sunlight.

§ 63-14 through § 63-21 are not required for a TGAI

64-1 Submittal of Samples

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.

Conclusions

1. Endurance 65WDG and Prodiamine 65WDG are identical formulations, however, each product is labeled for a different non-food use. Prodiamine [N^3,N^3-Di-n-propyl-2,4-dinitro-6(trifluoromethyl) -m-phenylenediamine], the active ingredient in both products, is not registered.

2. No permanent tolerances are established for Prodiamine. Petition PP#9F2236 is currently in reject status.

3. Temporary tolerances (all currently expired) were established at 0.1 ppm in or on: almond hulls; cottonseed; cottonseed forage; grapes; nuts; soybeans; soybean hay and forage; and stone fruit.

4. § 61-1: The Confidential Statement of Formula (CSF) for Endurance 65WDG, Prodiamine 65WDG and Prodiamine (technical) were submitted on EPA Form 8570-4 (revised 10-81). The registrant must resubmit the CSF's 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 (revised 10-81).

5a. § 61-2: The registrant has adequately described the beginning materials for the formulation of technical Prodiamine.

5b. § 61-2: The registrant has not adequately described the manufacturing process for technical prodiamine.

6a. § 61-3: The registant has adequately described the potential formation of impurities during the manufacture of technical Prodiamine.

6b. § 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.

7. § 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.

8. § 63-1 through 63-21: These requirements are adequately fulfilled for the technical material.

9. § 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.

Recommendation

For the reasons cited in conclusions: 4, 5b, and 7, we recommend against the registration of technical Prodiamine.

Attachment: Confidential Appendix (cc to S.F.,PM-23,R.F., Reviewer, and PMSD/ISB ONLY)

cc: Circu,R.F., Prodiamine S.F., PMSD/ISB
RDI:LC:11/20/86:RDS:11/20/86
TS-769:FBS:fbs:RM:710:CM#2:557-3044:11/21/86.

110201 PRODIAMINE RIN 1786-93

Page_____ is not included in this copy.

Pages 7 through 16 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.
