

US EPA ARCHIVE DOCUMENT

Shaughnessy Number: 110201

Date out of EFGWB: AUG 18 1989

To: Larry Schnaubelt, PM 23
Product Manager
Registration Division (H7505C)

From: Emil Regelman, Supervisory Chemist
Environmental Fate Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Thru: Hank Jacoby, Acting Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of...

Reg./File #: 55947-UR, 55947-UE, 55947-UG

Chemical Name: Prodiamine

Type Product: herbicide

Product Name: Endurance 65WDG

Company Name: Sandoz Crop Protection

Purpose: submission of data -- hydrolysis, aerobic soil metabolism, leaching/adsorption/desorption, dissipation, fish bioaccumulation

Date Received: 2/17/89

Action Code: 116

EFGWB#(s): 90365, -66, -67

Total Reviewing Time (decimal days): 6

Deferrals to: Ecological Effects Branch, EFED
 Science Integration and Policy Staff, EFED
 Non-Dietary Exposure Branch, HED
 Dietary Exposure Branch, HED
 Toxicology Branch

1. CHEMICAL:

chemical name: N³,N³-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine
common name: Prodiamine
trade name: Endurance
structure:
CAS #: 29091-21-2
Shaughnessy #: 110201

2. TEST MATERIAL: discussed under individual DERs

3. STUDY/ACTION TYPE:

hydrolysis, aerobic soil metabolism, leaching/adsorption desorption, soil and turf dissipation, fish bioaccumulation

4. STUDY IDENTIFICATION:

Bowman, B. R., and Fennessey, M., Determination of the Hydrolysis Rate of ¹⁴C-Prodiamine. performed by Analytical Bio-Chemistry Labs, Columbia, MO, sponsored and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 8/30/87. received EPA 4/19/88, MRID# 406091-01.

Kreuger, J.P., and Butz, R.G. Aerobic Soil Metabolism of Prodiamine. performed and submitted by Sandoz Crop Protection Corporation, Des Plaines, IL. dated 12/23/87. received by EPA 4/19/88 under MRID# 405934-24.

Daly, D., Soil/Sediment Adsorption-Desorption with ¹⁴C-Prodiamine. performed by Analytical Bio-Chemistry Labs, Columbia, MO, sponsored and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 10/22/87. received EPA 4/19/88, MRID# 405934-25.

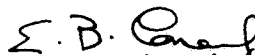
Daly, D., Soil/Sediment Adsorption-Desorption of Soil Incorporated with ¹⁴C-Prodiamine Following Aerobic Aging. performed by Analytical Bio-Chemistry Labs, Columbia, MO, submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 10/22/87. received EPA 4/19/88, MRID# 405934-26.

Smith, K., and Bade, T. Dissipation of Prodiamine in Soil. performed and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 4/7/88. received EPA 4/19/89, MRID# 405934-23.

Forbis, A., and Georgie, L., Uptake, Depuration and Bioconcentration of ¹⁴C-Prodiamine by Bluegill Sunfish (*Lepomis Macrochirus*). performed by Analytical Bio-Chemistry Labs, Columbia, MO, sponsored and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 11/11/85. received EPA 4/19/88, MRID# 405238-01.


5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP


8/16/89

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

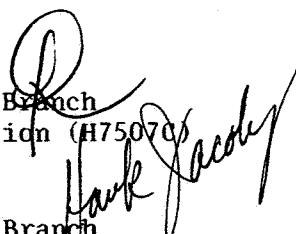

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 - Non-Dietary Exposure Branch, HED
 - Dietary Exposure Branch, HED
 - Toxicology Branch

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E. B. Conerly
8/16/89

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

Emil Regelman
AUG 18 1989

7. CONCLUSIONS:

The hydrolysis, aerobic soil metabolism, aged adsorption/desorption, and turf terrestrial field dissipation studies require additional information to become acceptable. The fish bioaccumulation study probably cannot be made acceptable.

8. RECOMMENDATIONS:

The applicant should submit acceptable soil photolysis, anaerobic soil metabolism and fish bioaccumulation data, and supply the following information:

- 1) confirmatory analyses for hydrolysis and aerobic soil metabolism studies
 - 2) adsorption/desorption data on aged prodiamine using analyses which follow all compounds separately
 - 3) analyses on uncomposited soil samples for the turf dissipation study
- Dietary Exposure Branch should evaluate the significance of the fish bioaccumulation findings.

9. BACKGROUND:

Prodiamine is a herbicide used to control the germination of grasses and broadleaf weeds in ornamentals and turf. The last review in the EFGWB (EAB) file (10/10/80) discussed a fish bioaccumulation study which was not accepted, and listed the following outstanding data requirements:

- 1) soil photodegradation
- 2) aerobic soil metabolism
- 3) anaerobic soil metabolism
- 4) effect of microbes on prodiamine -- no longer required by EFGWB

The status of data requirements is as follows:

hydrolysis -- discussed in this review -- additional information needed, but a half life in excess of 6 months is indicated at all three pHs
photolysis in water -- fulfilled 5/13/80 -- not done under current Guidelines. A short half life (ca. 20 min.) is indicated
soil photodegradation -- unacceptable 5/14/80
aerobic soil metabolism -- discussed in this review -- additional information needed, half-life ca. 2 mos, one major product
anaerobic soil metabolism -- unacceptable 5/14/80
leaching/adsorption/desorption -- discussed in this review, the acceptable unaged study indicates immobility in four soils, the unacceptable aged study suggests immobility in one soil
turf terrestrial field dissipation -- discussed in this review, information needed, no leaching or significant dissipation noted
confined accumulation on rotational crops -- satisfied 5/14/80 -- no significant accumulation except in root crops -- not done under current Guidelines
fish bioaccumulation -- discussed in this review, not acceptable, significant accumulation and slow depuration

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: See individual DERs.

11. COMPLETION OF ONE-LINER: attached

12. CBI APPENDIX: attached to individual DERs

DATA EVALUATION REVIEW 1

I. Study Type: hydrolysis

II. Citation:

Bowman, B.R., and Fennessey, M., Determination of the Hydrolysis Rate of ¹⁴C-Prodiamine. performed by Analytical Bio-Chemistry Labs, Columbia, MO, sponsored and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 8/30/87. received EPA 4/19/88, MRID# 406091-01.

III. Reviewer:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E.B. Conerly 8/16/89

IV. Conclusions:

The study may be acceptable if the applicant furnishes confirmatory information to verify the TLC method used for compound identification.

V. Materials and Methods:

test compounds -- Prodiamine uniformly ¹⁴C-labelled in the phenyl ring, 98.8% radiopure, before purification 25 mCi/mmol, after purification ?; analytical grade prodiamine

reference compounds -- despropyl prodiamine, and didespropyl prodiamine

test buffers

pH 5 -- acetic acid/acetate (ca. 0.1 M)

pH 7 -- tris/HCl (ca. 0.05 M), HEPES/KOH (ca. 0.01 M)

pH 9 -- boric acid/borax (ca. 0.01 M)

analytical methods

TLC -- precoated Merck RP-18F 2545, eluted with MeOH/H₂O (90/10)

LSC -- on spots scraped from TLC plates

VI. Study Author's Results and/or Conclusions:

¹⁴C-prodiamine, is slow to hydrolyze in the pH range 5-9. No significant degradation of the test compound was detected after 30 days of hydrolysis.

VII. Reviewer's Comments:

- 1) Identification of a compound by TLC in a single solvent is not usually definitive. Also, the TLC does not show the separation of a mixture of the three analytes. There could be some overlap under these conditions. Confirmatory analyses such as GC/MS are required.
- 2) EFGWB agrees that prodiamine does not show a pattern of degradation over the 30-day experiment. The prodiamine content appears to vary randomly rather than trending downward with time, as the low correlation coefficients for the linear regression equations ($r = 0.4-0.6$) demonstrate.

VIII. CBI Information Addendum: attached

110201

PRODIAMINE

RIN 1786-93

Page _____ is not included in this copy.

Pages 7 through 24 are not included.

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DATA EVALUATION REVIEW 2

I. Study Type: aerobic soil metabolism

II. Citation:

Kreuger, J.P., and Butz, R.G. Aerobic Soil Metabolism of Prodiamine. performed and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 12/23/87. received EPA 4/19/88, MRID# 405934-24.

III. Reviewer:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E.B. Conerly 8/16/89

IV. Conclusions:

This study may fulfill the requirement for aerobic soil metabolism data if the applicant supplies acceptable information to clarify and demonstrate the validity of the analytical method.

Prodiamine has a $t_{1/2}$ ca. 2 months under aerobic soil metabolism conditions in Kenyon loam.

V. Materials and Methods:

materials:

test compound -- uniformly ring labelled 14 -C prodiamine: 25.0 mCi/mmol, 98% radiopure, mixed as a solution with analytical standard to a spec. act. of 17600 dpm/ug
test soil -- Kenyon loam (characteristics in attached list)

methods

application -- @ 2.50 ug/gm
incubation -- in the dark; soil maintained @ 75% of 0.33 bar; 70% relative humidity, 25^o C. To trap volatiles, CO₂-free, water-saturated air was passed continuously from reaction chambers into ethylene glycol and KOH vessels.

sampling

soil -- 0, 1, 3, 7, 14 days, 1, 2, 3, 4, 6, 9, and 12 months
volatile traps -- as soil

extraction -- soil was extracted 2 x with MeOH, and then 2 x with Et₂O

analyses

TLC

MeOH extracts -- Hexane/EtOAc (7:3)

Et₂O extracts -- Hexane/EtOAc (8:2), developed 2 x

LSC -- TLC spots were scraped, eluted with MeOH and counted
GC/MS -- unchromatographed MeOH extracts; TLC spots

VI. Study Author's Results and/or Conclusions:

The half-life of prodiamine applied at a rate of 2.50 mg/gm in aerobic soil was 57 days. The only major metabolite was 6-amino-2-ethyl-7-nitro-1-propyl-

5-trifluoromethyl-benzimidazole (6-amino-benzimidazole). The benzimidazole concentration peaked at 0.82 ug/gm (93.2/8% of applied) at 270 days, and had declined to 0.74 ug/gm (29.6% of applied) at 365 days. Despropyl prodiamine reached a maximum of 0.09 ug/gm after 60 days. Reduced prodiamine reached a maximum of 0.03 ug/gm at 180-365 days. Unextractables increased with time to 0.9 ug/gm (36.8% of applied) by 365 days. Uncharacterized material at the TLC origin and with R_f lower than that of benzimidazole probably represented reaction products more than benzimidazole, and appeared only at low levels throughout the experiment.

Recovery of soil residues as determined by combustion ranged around 73% (+ %), apparently due to experimental error inherent in the combustion procedure.

Cumulative evolution of CO_2 amounted to 2.8% of the applied dose at 365 days.

Base extractable and EtOAc extractable were 6% and 13.6% respectively at 365 days.

Control soil treated with $HgCl_2$ as well as prodiamine showed no reduction in total radioactivity in 365 days.

VII. Reviewer's Comments:

- 1) The long-lived degradates may be more of a concern than parent compound, which is only moderately stable to metabolism. EFGWB defers to Residue and Tox branches to make this determination.
- 2) Table VI (attached) requires clarification. The separation achieved by these TLC solvent systems is somewhat marginal. Also, it is not clear whether the systems mentioned as D through G were used once (for a total of two developments/plate) or twice each (for a total of four developments/plate), and whether the TLC plates were developed in one or two dimensions. (From the examples in the submission, this reviewer concludes that the TLCs were one-dimensional.)
- 3) The significance of the applicant's statement that the "sterile" soil showed no loss of total radioactivity is obscure, unless it is intended to imply that some microbial action in the "live" samples renders a portion of radioactivity unrecoverable.

VIII. CBI Information Addendum: attached

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DATA EVALUATION REVIEW 3

I. Study Type: adsorption/desorption

II. Citation:

Daly, D., Soil/Sediment Adsorption-Desorption with ¹⁴C-Prodiamine. performed by Analytical Bio-Chemistry Labs, Columbia, MO, sponsored and submitted by Sandoz Crop Protection Corporation, Des Plaines, IL. dated 10/22/87. received EPA 4/19/88, MRID# 405934-25. reviewed below as "UNAGED STUDY"

Daly, D., Soil/Sediment Adsorption-Desorption of Soil Incorporated with ¹⁴C-Prodiamine Following Aerobic Aging. performed by Analytical Bio-Chemistry Labs, Columbia, MO, sponsored and submitted by Sandoz Crop Protection Corporation, Des Plaines, IL. dated 10/22/87. received EPA 4/19/88, MRID# 405934-26. reviewed below as "AGED STUDY"

III. Reviewer:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E.B. Conerly 8/16/89

IV. Conclusions:

The unaged study fulfills the leaching/adsorption/desorption data requirement, although it did not include the soil used in the aerobic metabolism study. It indicates immobility in all four soils tested:

sand	--	$k_{ads} = 19.54$	$k_{OC} = 19540$
silt loam	--	$k_{ads} = 54.47$	$k_{OC} = 10890$
clay loam	--	$k_{ads} = 181.6$	$k_{OC} = 9310$
sandy loam	--	$k_{ads} = 398.5$	$k_{OC} = 12860$

The aged study does not fulfill the data requirement for two main reasons:

- 1) It did not test four different soil types.
- 2) It measured only the total combined radioactivity of parent and major degradate.

The data do suggest that both compounds are immobile in Kenyon loam. The aged mixture should be tested in four soil types using analytical methods which distinguish between parent and degradate.

V. Materials and Methods:

UNAGED STUDY

test compound -- spec. act. 25 mCi/mmol, 95.2% radiopure
stock solution -- above dissolved in 100 ml MeOH to give 59.4 ug/ml
test solutions -- 0.0 (control), 0.006, 0.013, 0.020, 0.025, 0.030 ug/ml
test soils -- sand, silt loam, clay loam, sandy loam (details attached)
air dried and sieved through a 10 mesh screen
adsorption procedure -- 2 gm/25 ml solution shaken for 22 hours for sand, silt loam, clay loam; 1 gm/25 ml shaken for 43 hours for sandy loam; equilibrated suspensions were centrifuged and filtered, and the supernatants removed

desorption procedure -- after replacement of supernatant removed in the step above with an equal volume of 0.01 M CaCl₂, the resuspended soil pellets were shaken to equilibration (65 hours for sandy loam, and 20 hours for the others). The suspensions were then centrifuged and filtered as above.

analytical techniques

LSC -- total radioactivity in supernatants and combusted soils

AGED STUDY

Extractable material from prodiamine-treated soil was adsorbed on Kenyon loam soil, and K_ds and K_{oc}s of adsorption and desorption determined.

test material -- ¹⁴C-prodiamine applied to soil at 3.02 ug and 53,000 dpm/gm dry soil, supplied by the sponsor as aged aerobically for 30 days. The soil was extracted 2 x with MeOH (1 ml/gm soil) with shaking and filtered. Extracts were analyzed for total radioactivity, and the extracted soil was combusted for determination of residual radioactivity.

VI. Study Author's Results and/or Conclusions:

UNAGED STUDY

Adsorption/desorption studies on prodiamine using four different soils -- sand, silt loam, clay loam, and sandy loam -- indicated immobility, k_ds for adsorption ranging from 19.54 in sand to 398.5 in sandy loam. Since the absorbances were outside the linear range for the Freundlich model, a linear isotherm model was applied. The mean mass balance accountability for applied radioactivity was 94.1%.

AGED STUDY

The extract contained 69.4% prodiamine, and 21.8% prodiamine benzimidazole. The degradate identity was confirmed by GC/MS. [Combined] K_dads of 117.4, K_ddes of 210.7, K_{oc}ads of 5340, and K_{oc}des of 9580, indicated immobility. Mean recovery of radioactivity was 93.4% + 6.93%.

VII. Reviewer's Comments:

UNAGED STUDY

- 1) The tested soils did not include that used for the metabolism study, but did encompass its range of characteristics.
- 2) Although the mean recoveries are as described, those from sand are consistently lower, averaging 79.8+ 3.61%. Also, the variability of recovery in the sandy loam samples is ca. 20%, with the recoveries themselves ranging from 88.3% to 162%. The highest value (162%) is a statistical outlier [deviation > 4x the std. dev. from the mean calculated without that value]. This does not materially affect the interpretation of the results.

AGED STUDY

The study provides only supplementary information, since just one soil was tested, and four different ones are required. Immobility of both compounds is suggested by the results.

VIII. CBI Information Addendum: attached

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DATA EVALUATION REVIEW 4

I. Study Type: soil dissipation on turf

II. Citation:

Smith, K., and Bade, T. Dissipation of Prodiamine in Soil. performed and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 4/7/88. received EPA 4/19/89, MRID# 405934-23.

III. Reviewer:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E.B. Conerly

8/16/89

IV. Conclusions:

The study does not fulfill the data requirement, but may be acceptable if analyses on the control plot and uncomposited soil samples are supplied.

V. Materials and Methods:

test material -- commercial sample of a 65WDG (water dispersible granular) application -- at 2.0 lb/A (maximum label rate) to two 6 x 50 ft plots of bermuda grass on sandy loam. Control plot 100 ft west upslope sampling -- immediately, and 1, 15, 30, 60, and 120 days post treatment

VI. Study Author's Results and/or Conclusions:

Leachability and dissipation were determined for prodiamine and its 6-aminoimidazole metabolite after turf application. Because the day zero values were less than the application rate and subsequent values, these data were omitted from linear regression analyses. The metabolite was detected only in the 0-10 cm depth at 60 and 120 days post-application. No prodiamine was found beyond 10 cm except for 4 samples near the limit of detection, which were ascribed to contamination during sampling. The projected half-life was ca. 230 days. These findings indicate low leachability of parent and metabolite, consistent with solubility and laboratory leaching data for these compounds.

VII. Reviewer's Comments:

- 1) The study does not fulfill the turf field dissipation data requirement at this time, because of the compositing of samples. Compositing soil samples as a means of "minimizing variability" is not acceptable. In this case the composited samples (reps 2 and 3) were more variable than the single samples (reps 1). If uncomposited reps 2 and 3 samples are available, they should be analyzed and the results submitted to EFGWB.
- 2) [See highlighted text above.] The amount of material reaching the soil from a turf application would not be expected to be uniform. This observation does not invalidate the study.
- 3) No analytical values were supplied for the control plot.

VIII. CBI Information Addendum:

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PRODIAMINE

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DATA EVALUATION REVIEW 5

I. Study Type: fish bioaccumulation

II. Citation:

Forbis, A., and Georgie, L. Uptake, Depuration and Bioconcentration of C¹⁴-Prodiamine by Bluegill Sunfish (*Lepomis Macrochirus*). performed by Analytical Bio-Chemistry Labs, Columbia, MO, sponsored and submitted by Sandoz Crop Protection Corp., Des Plaines, IL. dated 11/11/85. received EPA 4/19/88, MRID# 405238-01.

III. Reviewer:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E-B. Conerly 8/18/89

IV. Conclusions:

This study does not fulfill the data requirement, since the concentration of prodiamine to which the fish were exposed varied by a factor of 4 during the experiment. Further, there may be an unacceptable human dietary exposure risk since the fish retain a significant percentage of the accumulated residues after exposure is stopped -- 20% remains after 14 days depuration.

V. Materials and Methods: not reviewed in detail since the study is clearly invalid due to the variability of prodiamine content to which the fish were exposed.

VI. Study Author's Results and/or Conclusions:

Accumulation in the fish reached a steady state at about day 14, with bioconcentration factors (BCFs) of 53-570 for fillet, 130-1900 for whole fish, and 190-2900 for viscera. Depuration resulted in 81, 91, and 92% clearance of these tissues in 14 days. A non-linear two-compartment (water and fish) kinetic modeling program (BIOFAC) predicted a BCF of 1400 for whole fish, and a time to 90% steady state of 11.3 ± 0.778 days. These theoretical values are in good agreement with experimental observations.

VII. Reviewer's Comments:

- 1) The study is not acceptable since the concentration of compound in the water was very variable [see attached details]. The data suggest, but do not clearly demonstrate, that accumulation reached a plateau.
- 2) The edible portion (fillet) retained ca. 20% of the accumulated residue after 14 days depuration. EFGWB defers to the Dietary Exposure Branch as to the significance of this finding.

VIII. CBI Information Addendum: attached

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PRODIAMINE

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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.
