

263110

Record No.

Review No.

110201-1

Shaughnessey No.

EEB REVIEW

DATE: IN 4/30/90 OUT 8/24/90

FILE OR REG. NO. 55947-UR

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 4/13/90

DATE RECEIVED BY EFED 4/27/90

RD REQUESTED COMPLETION DATA 8/20/90

EEB ESTIMATED COMPLETION DATE 8/20/90

RD ACTION CODE/TYPE OF REVIEW 116

TYPE PRODUCTS(S): I, D, H, F, N, R, S Herbicide

MRID NO(S). 414516-01

PRODUCT MANAGER NO. 23 Joann Miller

PRODUCT NAME(S) Technical Prodiamine

COMPANY NAME Sandoz

SUBMISSION PURPOSE Review & comment on registrant's

Aquatic Risk Assessment

SHAUGHNESSEY NO.

CHEMICAL AND FORMULATION

% A.I.

110201-1

Prodiamine

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

SUBJECT: Review and Comment on Aquatic Risk Assessment

FROM: James W. Akerman, Chief
EFED/EEB

THRU: Product Manager, Joanne Miller, PM 23,
Registration Division H7507C

TO: Sandra J. Gowanlock, Manager
State and International Registrations
Regulatory Affairs

The Ecological Effects Branch (EEB) has reviewed and evaluated the results of a co-solvent solubility study and an aquatic risk assessment for the herbicide prodiamine. In addition, EEB has provided herewith a list of required studies.

Results from co-solvent solubility tests done at Sandoz indicate that acceptable solubility of prodiamine (technical) and formulated product, 65WDG may be achieved with 0.05% and 1.0% polyethylene glycol (PEG) respectively. The precipitate seen with the 65 WDG is of concern to EEB. Can the precipitate be identified? Is the precipitate parent material or additive? EEB would like answers to these questions if possible. Nevertheless, it would appear that PEG is viable for dissolving technical material. EEB concurs with using 0.05% PEG as co-solvent for prodiamine technical in required toxicity studies.

Sandoz also submitted an aquatic risk assessment (Lin and Butz; Accession No. 414516-01) for review by EEB. EEB and the Environmental Fate and Groundwater Branch (EFGWB) have reviewed the risk assessment and disagree with several conclusions derived by Sandoz.

Sandoz concluded that worst case runoff loading would result in an initial concentration in water of 0.9120 ppb dissipating to 0.0917 ppb at the end of 96 h. EFGWB estimated the worst case runoff initial concentration to be 13 ppb (calculated value = 32 ppb) dissipating to 10.6 ppb after 96 h. Using SWRRB, EFGWB determined maximum loading to be 5.810×10^2 lb/A, which was 35.1 times higher than the loading determined by Sandoz. EFGWB ran the EXAMS simulation using photolysis and advection data and determined that the half-life for photolysis was 412 h and the half-life for advection was 755.8 h.

CONCURRENCES			
SYMBOL	H7507C Other	H7507C	H7507C
SURNAME	J. Bailey	C. Gowanlock	A. Akerman
DATE	8-24-90	8/29/90	9/4/90
EPA Form 1320-1 (12-70)			

OFFICIAL FILE COPY

(photolysis rate), whereas EFGWB's value is lower (4.16/h vs 2.08/h) and 2) the half-life determined by EFGWB (20 min) was twice as long as that determined by Sandoz (10 min). If data is unavailable to support KBAC and QUA estimates, Sandoz should submit protocols to EFGWB. Sandoz also needs data to support dissipation values. If you have questions, you may contact Bob Hitch (Surface Water Section, EFED/EFGWB).

To date EEB has only one acceptable study for prodiamine. Below are studies reviewed by EEB and their status.

<u>Species</u>	<u>%AI</u>	<u>LC50/LD50 mg/Kg</u>	<u>Author</u>	<u>Date</u>	<u>MRID#</u>	<u>Fulfills Guideline Requirements</u>
Rainbow Trout	Tech	6.6	McAlliser et al.	1985	260681	NO
Bluegill	Tech	68.0	Cohle & McAllister	1985	260681	NO
D. magna	Tech	29.0	Forbis, et al.	1985	260681	NO
Mysid	Tech	2.1	Burgess	1987	405934-06	NO
Bobwhite Quail (dietary)	Tech	>10K ppm	Truslow Farms, Inc	1975	260681	YES
Mallard duck (Oral)	Tech	>10K mg/kg	IBT Labs	1975	260681	NO
Bobwhite Quail (Oral)	Tech	>10K mg/kg	IBT Labs	1975	260681	NO
Bobwhite Quail (Oral)	Tech	2250	Grimes & Jaber	1987	402293-03	YES

Prodiamine is toxic to fish at concentrations below 100 ppm. The EEC (10.6 ppb @ 96 h) would exceed 0.01 of the LC50 and water solubility is below 0.5 ppm. In addition, prodiamine has a K_{ow} greater than 1000, a half-life greater than 4 days, is somewhat persistent, and stable to hydrolysis. EEB therefore at this time requires the following studies.

1. One fish acute LC50 study.
2. A chronic Daphnia study
3. Fish Early Life Stage study

Additional requirements or waivers will be determined upon review of the above studies. If you have any questions, please direct them to Tom Bailey (703-557-1666) or Henry Craven (703-557-0320).

Out: 17 Aug 90

Shaugnessy Numbers: 110201

TO: Product Manager, Joanne Miller (PM-23)
Registration Division (H7505C)

FROM: Catherine Eiden, Head, *Catherine Eiden*
Surface Water Section
Environmental Fate and Groundwater Branch (H-7507C)

THRU: Henry Jacoby, Chief, *Henry Jacoby*
Environmental Fate and Groundwater Branch (H-7507C)

Attached, please find the EFGWB review of:

Reg./File #: 263110

Chemical Name: Prodiamine

Type Product: Herbicide

Company Name: SANDOZ

Purpose: Respond to Ecological Effects Branch
with review of SWRRB and EXAMS
simulation

Not a formal registration action
received from EEB approximately
18 July 1990

Date Received: _____

Action Code: NA

Date Completed: 1 Aug 1990

EFGWB #(s): NA

Monitoring Study Requested: No Total Reviewing Time: 3 Days

Monitoring Study Volunteered: No

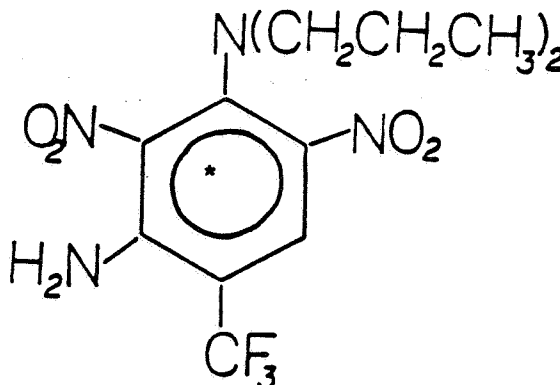
No Deferrals to any other Branch

5

I. Chemical:

Common Name: Prodiamine

Chemical Name: N3, N3-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylene diamine



II. Test Material:

The only formulation is 65 WDG. That is 65% active ingredient in a water dispersible granule.

III. Action Type

Review of Registrant's SWRRB and EXAMS simulation.

IV. Study ID:

Lin, J.C. and R. G. Butz. Preliminary report. Aquatic risk assessment for prodiamine use of turf.
USEPA Accession 414516-01.

V. Reviewed By: Robert K. Hitch
EFGWB

Signature: *Robert K. Hitch*

Date: 3 Aug 90

VI. Approved By: Catherine Eiden, Chief
Surface Water Section
EFGWB

Signature: *Catherine Eiden*

Date:

8/10/90



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

1 August 1990

MEMORANDUM

SUBJECT: Review of Sandoz Corp Estimated Environmental
Concentration (USEPA Accession 414516-01)

From: Robert K. Hitchcock, R. K. Hitchcock
Surface Water Section
EFGWB/EFED

THRU: Catherine Eiden, Chief, Catherine Eiden
Surface Water Section
EFGWB/EFED

THRU: Henry Jacoby, Chief,
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division

TO: Tom Bailey, Fishery Biologist,
EEB/EFED/OPP H7507C

and

Joanne Miller, PM 23,
Registration Division H7505C

Please find attached our review of said document. To summarize, we project that in a pond with the characteristics of the Athens AERL pond, the concentration of prodiamine dissolved in the water column would reach 13 ppb immediately after a worst case runoff loading and that this would dissipate to 10.6 ppb after 96 hours. Additionally, we require specific studies to support the estimates of average concentration projected by the registrant in Accession 414516-01.

If either of you have additional questions, please do not hesitate to call me (557-0991).

cc: EFGWB registration files

VII. Conclusions:

For the standard USEPA Athens Georgia AERL pond and based on the average loading projected by SWRRB (1.655×10^{-3} lb/ac), the registrant projects that the dissolved concentration of prodiamine in the water column would reach a maximum of 0.9120 ppb at 0 hr after a spike loading and decline to 0.0917 ppb at the end of 96 hours. The EFGWB requires that the registrant present studies to support the KBAC (biolysis) and QUA (photolysis quantum yield) used in their EXAMS simulation. Once studies supporting these parameters are submitted, the registrant's simulation of average concentration will be fully supported.

Additionally we calculate the the $1/2$ life as 20 minutes (see one-liner attached) rather than the 10 minutes used by the registrant, and the Kdp would be 2.08/hr rather than the 4.16/hr used by the registrant.

Additionally, EFGWB concludes that, given the prodiamine fate data currently in our files, we would estimate that the highest prodiamine concentration (dissolved, in water column would be 13 ppb at 0 hr after the maximum spike loading and, would decline to 10.6 ppb 96 hours after the spike.

VIII. Recommendations:

If the registrant does not have experimental data to support his KBAC and QUA estimates, it is recommended that the registrant submit study protocols to EFGWB prior to beginning lab work. The registrant should note on the protocols that they are to be used in developing the KBAC and QUA terms for EXAMS modeling purposes.

IX. Background:

The registrant is attempting to register prodiamine on turf (EUP label attached). In the current submission, the registrant presents estimates of environmental concentrations based on this use. In his memorandum of 18 July 1990 (Attached), Tom Bailey of EEB asks that EFGWB review the registrant's estimates.

We currently have a fully acceptable photolysis study showing rapid degradation of prodiamine in water exposed to natural sunlight. Fully acceptable studies also indicate that prodiamine is stable to hydrolysis and moderately bound to sediment (see "one-liner" summary sheet attached). At this time, we have no aerobic or anaerobic metabolism studies.

X. Discussion

Looking at the registrant's SWRRB analysis, we note that the maximum loading projected is 5.810×10^{-2} lb/ac which is 35.1 times higher than the average loading used by the registrant. If this could be loaded directly into the pond*, the dissolved water concentration would be about 32 parts per billion. However, this exceeds the aqueous solubility limit which is 13 ppb. EFGWB, therefore, considers 13 ppb dissolved in the water column as the worst case concentration. The registrant assumes for his average condition that biodegradation is rapid. EFGWB has no aquatic metabolism studies on file for prodiamine. As a worst case, we would assume that there are no dissipative processes except photolysis (which is supported by tests on file except that there is no estimate of the quantum yield) and advection (i.e. being carried away by the flow of the stream discharging from the pond). Running EXAMS with only these two dissipative processes, we see that the half-life for photolysis is 412 hours and the half-life for advection is 755.8 hours (Tables 1.01.1 and 18.01 from the EFGWB EXAMS run are attached). Using 1st order kinetics to hand calculate* the concentration at the end of 96 hrs, we derive 10.6 ppb:

$$1/412\text{hr} + 1/755.8\text{hr} = 1/X \text{ or } X = 266.5 \text{ hrs.}$$

where X = overall half-life

The overall dissipation rate constant or k is therefore

$$0.693/266.5 \quad \text{or, } k = 2.6 \times 10^{-3}$$

The concentration at the end of

$$\begin{aligned} 96 \text{ hrs, } C_{96} &= C_0 e^{-kt} \\ &= (13\text{ppb})e^{(-2.6 \times 10^{-3})(96)} \\ &= 10.6 \text{ ppb.} \end{aligned}$$

*Generally EXAMS EECs vary linearly with the magnitude of loading, but this is not true when the EEC would exceed 1/2 of the solubility. When the EEC would exceed 1/2 of the solubility, the program lowers the loading to the point that the concentration of prodiamine (dissolved in the water column which occurs immediately after the spike will equal one-half the solubility limit. This is to help ensure that pseudofirst order kinetics are appropriate. At higher concentrations pseudo-first order kinetics may not be appropriate. Our hand calculations are based on pseudo-first order kinetics for lack of a better assumption.

XI. Confidential Appendix

NA

XII One-Liner

NA

Prodiamine

Page 11 is not included in this copy.

Pages _____ through _____ 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.

```

*** Chemical-specific data: SET via "entry( 1)"
MWT: 3.50E+02 VAPR: HENRY: KOW:
KVO: EVPR: EHEN: KOC:
*** Ion-specific data: "entry(1, 1)"
SOL: 1.30E-02 KPB: KPS: 1.82E+02
ESOL: KPDOC:
*** Reactivity of dissolved species: SET via "entry(1, 1, 1)"
KAH: EAH: KNH: ENH:
KBH: EBH: KRED: ERED:
KBACW: QTBAW: KBACS: QTBAS:
*** Reactivity of solids-sorbed species: "entry(2, 1, 1)"
KAH: EAH: KNH: ENH:
KBH: EBH: KRED: ERED:
KBACW: QTBAW: KBACS: QTBAS:
*** Reactivity of "DOC"-complexed species: "entry(3, 1, 1)"
KAH: EAH: KNH: ENH:
KBH: EBH: KRED: ERED:
KBACW: QTBAW: KBACS: QTBAS:
*** Reactivity of biosorbed species: "entry(4, 1, 1)"
KBACW: QTBAW: KBACS: QTBAS:

```

```

Photochemical process data; Ion-specific data: "entry(1, 1)"
KDP(1, 1): 2.08E+00 RFLAT(1, 1): 32.8 LAMAX(1, 1): 0.0
*** Reactivity of dissolved species: SET via "entry(1, 1, 1)"
K1O2: EK1O2: KOX: EOX:
*** Reactivity of solids-sorbed species: "entry(2, 1, 1)"
K1O2: EK1O2: KOX: EOX:
*** Reactivity of "DOC"-complexed species: "entry(3, 1, 1)"
K1O2: EK1O2: KOX: EOX:
QUA(1,1, 1) 5.00E-02 QUA(2,1, 1) QUA(3,1, 1)

```

```

Light ABSORption (n,1, 1): (1) (2)
(3) (4) (5) (6)
(7) (8) (9) (10)
(11) (12) (13) (14)
(15) (16) (17) (18)
(19) (20) (21) (22)
(23) (24) (25) (26)
(27) (28) (29) (30)
(31) (32) (33) (34)
(35) (36) (37) (38)
(39) (40) (41) (42)
(43) (44) (45) (46)

```

Exposure Analysis Modeling System -- EXAMS Version 2.93, Mode 2
Chemical: 1) prodiamine

minima at the end of 96. hours. Number in parens (Seg) indicates segment where value was found.

	Total Seg mg/*	Dissolved Seg mg/L **	Sediments Seg mg/kg	Biota Seg ug/gram
Water Column:				
Mean	3.318E-03	3.300E-03	0.601	0.000E-01
Max (1)	3.318E-03	(1) 3.300E-03	(1) 0.601	(1) 0.000E-01
Min (1)	3.318E-03	(1) 3.300E-03	(1) 0.601	(1) 0.000E-01
Benthic Sediments:				
Mean	4.446E-02	2.438E-04	4.437E-02	0.000E-01
Max (2)	4.446E-02	(2) 2.438E-04	(2) 4.437E-02	(2) 0.000E-01
Min (2)	4.446E-02	(2) 2.438E-04	(2) 4.437E-02	(2) 0.000E-01

* Units: mg/L in Water Column; mg/kg in Benthos.

** Includes complexes with "dissolved" organics.

Exposure Analysis Modeling System -- EXAMS Version 2.93, Mode 2

Ecosystem: Pond -- AERL code test data -- mean values only

Chemical: prodiamine

Table 18.01. Sensitivity analysis: after 96 hours.

Current Value by Process	Mass Flux Kg/ hour	% of Total Flux	Half-Life* hours
Hydrolysis			
Reduction			
Radical oxidation			
Direct photolysis	1.6213E-04	64.72	412.0
Singlet oxygen oxidation			
All Chemical Processes	1.6213E-04	64.72	412.0
Bacterioplankton			
Benthic Bacteria			
Total Biolysis			
Surface Water-borne Export	8.8383E-05	35.28	755.8
Seepage export			
Volatilization			
=====			
Total mass flux:	2.5051E-04		

Prodiamine

Page 14 is not included in this copy.

Pages _____ through _____ 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.

ENVIRONMENTAL FATE & GROUND WATER BRANCH
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY

Page 1

Common Name: **PRODIAMINE** Date: 06/21/90
Chem. Name : N3,N3-Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylen
: e diamine
Shaugh. # : 110201 CAS Number: 29091-21-2
Type Pest. : HERBICIDE
Formulation:
Uses : TO CONTROL THE GERMINATION OF GRASSES AND BROADLEAF WEEDS
: IN OORNAMENTALS AND TURF
:

Empir. Form: $C_{13}H_{17}N_4O_4F_3$
Mol. Weight: 350.3
Solub.(ppm): .05 @ $0^{\circ}C$

VP (Torr): 2.5E-7
Log Kow : 3.3E4

Henry's :

Hydrolysis (161-1)

pH 5:[*] STABLE

pH 7:[*] STABLE

pH 9:[*] STABLE

pH :[]

pH :[]

pH :[]

Photolysis (161-2, -3, -4)

Air :[]

Soil :[]

Water:[*] ABOUT 20 MINUTES

: []

: []

: []

MOBILITY STUDIES (163-1)

Soil Partition (Kd)

1.[] SOIL Kads

2.[*] SAND 19.54

3.[*] SILT LOAM 54.47

4.[*] CLAY LOAM 181.6

5.[*] SANDY LOAM 398.5

6.[] (UNAGED STUDY)

Koc

19,540

10,890

9,310

12,860

Rf Factors

1.[]

2.[]

3.[]

4.[]

5.[]

6.[]

METABOLISM STUDIES (162-1,2,3,4)

Aerobic Soil (162-1)

1.[#] ABOUT 2 MONTHS

2.[]

3.[]

4.[]

5.[]

6.[]

7.[]

Anaerobic Soil (

1.[]

2.[]

3.[]

4.[]

5.[]

6.[]

7.[]

Aerobic Aquatic (162-4)

1.[]

2.[]

3.[]

4.[]

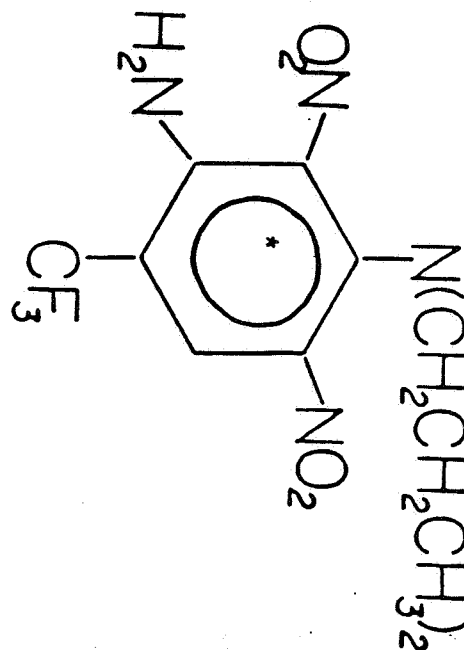
Anaerobic Aquatic (162-3)

1.[]

2.[]

3.[]

4.[]



[*] - Acceptable Study. [#] = Supplemental Study

Prodiamine

Page _____ is not included in this copy.

Pages 16 through 28 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.



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

JUL 18 1990

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Review of Modeling (SWRRB AND EXAMS) Procedures and Results Submitted by Registrant.

FROM: Tom A. Bailey, Fishery Biologist
EEB/EFED/OPP

Thru: James W. Akerman, Chief *H.T. Craven*
Ecological Effects Branch
Environmental Fate and Effects Division

TO: Henry Jacoby, Chief
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division

Attached please find the document, "Preliminary Report, Aquatic Risk Assessment for Prodiamine use of Turf" (sic). This Risk Assessment was submitted to EPA by Sandoz Crop Protection Corporation for evaluation. Since this is a new chemical, EEB requests that EFGWB review the SWRRB/EXAMS modeling procedures used and results obtained by Sandoz for the herbicide, Prodiamine. Due to an agreement made by RD, we will need your response by August 6, 1990, if possible. If you have questions, please contact Tom A. Bailey (557-1666) or Harry T. Craven (557-0320). Thank you for your cooperation.