

Shaughnessy Number: 028201
~~078701~~

Date out of EFGWB: 5/6/92

To: Product Manager 71 (Waldrop/Stowe)
Reregistration Division

From: Akiva Abramovitch, Head
Environmental Fate Review Section #3
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

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

Attached, please find the EFGWB review of...

Reg./File #: n.a.

Chemical Name: Propanil

Type Product: herbicide

Product Name: n.a.

Company Name: Rohm and Haas

Purpose: request for review of existing environmental fate data -- evidence of production of 3,3',4,4'-tetrachloroazobenzene (TCAB)

Date Received: 4/23/92 EFGWB#(s): 92-0770 Reviewing Time (decimal days): 0.5

EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

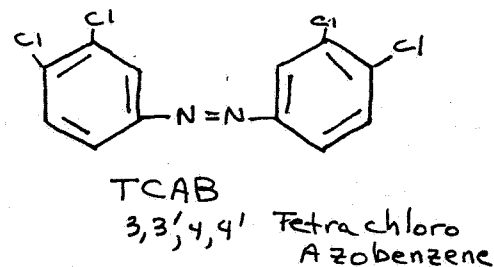
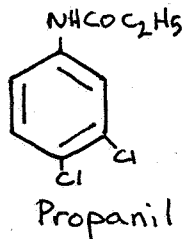
161-1	162-4	164-4	166-1
161-2	163-1	164-5	166-2
161-3	163-2	165-1	166-3
161-4	163-3	165-2	167-1
162-1	164-1	165-3	167-2
162-2	164-2	165-4	201-1
162-3	164-3	165-5	202-1

Y = Acceptable (Study satisfied the Guideline)/Concur
P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
S = Supplemental (Study provided useful information, but Guideline was not satisfied)
N = Unacceptable (Study was rejected)/Non-Concur

bcp

1. CHEMICAL:

chemical name: 3,4-dichloropropionanilide, N-(3,4-dichlorophenyl) propanamide
common name: Propanil
trade name: n.a.
structure:
CAS #: 709-98-8
Shaughnessy #: 28201



2. TEST MATERIAL: n.a.

3. STUDY/ACTION TYPE: n.a.

4. STUDY IDENTIFICATION: n.a.

5. REVIEWED BY:

Typed Name: E. Brinson Conerly-Perks
Title: Chemist, Review Section 3
Organization: EFGWB/EFED/OPP

E. B. Conerly-Perks
5/1/92

6. APPROVED BY:

Typed Name: Akiva Abramovitch
Title: Head, Review Section 3
Organization: EFGWB/EFED/OPP

Akiva Abramovitch
MAY 1 1992

7. CONCLUSIONS:

The available data (hydrolysis, photolysis, anaerobic and aerobic aquatic metabolism studies) indicate that TCAB has not been detected as a metabolite. In two field dissipation studies which have not yet reviewed, the soil was only analyzed for Propanil and 3,4-dichloroaniline, presumably because no TCAB had been detected in the metabolism studies. Rotational crop studies are still pending.

8. RECOMMENDATIONS:

Since TCAB is a matter for concern, the Propanil Task Force and other interested parties should be so informed. Current and ongoing studies should be performed with special emphasis on making sure this metabolite is detected if it is present. Of special interest is the possibility of accumulation in rotated crops.

EFGWB will not require any special studies at this time, but it is very important that studies already identified as required should be submitted in a timely fashion.

If the investigators have retained samples from the field dissipation studies, they may wish to attempt to analyze for TCAB in these samples, if only to confirm that there is none there. An acceptable storage stability study would also be necessary for validation of any results from these analyses.

9. BACKGROUND:

A researcher in Arkansas has submitted data regarding a cluster of human reproductive problems in an area of high Propanil use, and has raised the question whether these findings might be attributable to TCAB. EFGWB was asked to review the available data for information on TCAB, and to determine whether any special data might be needed.

Because of the structure of Propanil, TCAB was identified in studies submitted by the Propanil Task Force as a possible metabolite. However, according to the available studies (hydrolysis, aqueous photolysis, anaerobic and aerobic aquatic metabolism) it has not been detected. Although values were reported for it in the two metabolism studies, no actual peaks were observed. The values were derived by totalling counts above background in the chromatographic areas where the TCAB peak would have been found. These numbers served to establish a maximum possible concentration of less than 0.1 ppm. Extracts were analyzed by TLC in two solvent systems, and by HPLC.

The data base is too incomplete to perform a valid ground or surface water assessment at this time. A summary of EBC 1/10/92 is attached which gives more details.

ENVIRONMENTAL FATE ASSESSMENT

The data base on Propanil is still very incomplete at this time. Propanil is stable to hydrolysis in the laboratory, and to unsensitized aqueous photolysis. Based on partially acceptable studies, it is rapidly metabolized under aerobic or anaerobic conditions in a water/sediment milieu, and undergoes hydrolysis at a moderate rate in the same water/sediment system. A more complete discussion may be found in EBC 1/10/92, pages 2-5 (attached).

Data requirements for aquatic food use (i.e. rice) and their status is as follows:

hydrolysis -- stable at pH 5, 7, and 9. fulfilled by MRID 410666-01 (pH 5), and in the Registration Standard 1987 (pH 7, 9).

photolysis in water -- partially fulfilled, MRID 410707-01. The study provides the supplemental information that Propanil is stable for 30 days to unsensitized photolysis in water

anaerobic aquatic metabolism -- partially fulfilled, MRID 418726-01. The study provides the supplemental information that Propanil is rapidly metabolized under anaerobic conditions ($t_{1/2}$ = 2-3 days)

aerobic aquatic metabolism -- partially fulfilled, MRID 418487-01. The study provides the supplemental information that Propanil is rapidly metabolized under aerobic conditions ($t_{1/2}$ = 2 days)

leaching/adsorption/desorption -- pending, also required for terrestrial crop use; will be submitted by the Propanil Task Force

crop use; will be submitted by the Propanil Task Force

aquatic field dissipation -- pending, will be submitted by the Propanil Task Force

long term field dissipation -- conditionally required, if the conventional short term field dissipation study so indicates

confined accumulation on rotational crops -- pending, will be submitted by the Propanil Task Force

field accumulation on rotational crops -- requirement reserved pending results of confined study, also required for terrestrial uses, as noted below

confined accumulation on irrigated rotational crops -- pending

fish bioaccumulation -- waiver recommended due to low k_{ow} and applicant's affirmation of low accumulation in fathead minnows

The several additional studies required to support registration on terrestrial crops include the following:

photodegradation on soil -- NOT FULFILLED -- not supported by the Propanil Task Force

aerobic soil metabolism -- partially fulfilled, supplemental information provided by MRID 415387-01, reviewed EBC 12/3/90

anaerobic soil metabolism -- partially fulfilled by the anaerobic aquatic metabolism study. The study provides the supplemental information that Propanil is rapidly metabolized under anaerobic conditions ($t_{1/2}$ = 2-3 days).

terrestrial field dissipation -- NOT FULFILLED -- will not be supported by the Propanil Task Force

accumulation in confined rotational crops -- NOT FULFILLED -- will be supported by the Propanil Task Force for rice

accumulation in field rotational crops -- reserved, pending review and evaluation of the confined study

Because of informal reports that Propanil applied to rice subsequently reached and damaged non-target crops, especially prune trees, EFGWB also requires the following studies, which are not usually imposed for aquatic uses:

lab volatility

spray drift

droplet size spectrum

drift field evaluation

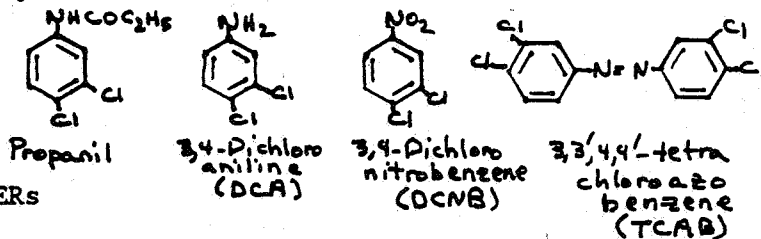
downwind monitoring of deposition on other crops

According to the 1987 Registration standard, 95% of the manufactured product is used on rice. The Propanil Task Force does not intend to support the terrestrial food uses (i.e. the 5% which is not rice).

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: n.a.
11. COMPLETION OF ONE-LINER: no information added
12. CBI APPENDIX: informational material attached

1. CHEMICAL:

chemical name: 3,4-dichloropropionanilide, N-(3,4-dichlorophenyl) propanamide
common name: Propanil
trade name: n.a.
structure:
CAS #: 709-98-8
Shaughnessy #: 28201



2. TEST MATERIAL: described in DERs

3. STUDY/ACTION TYPE:

91-0619 -- submission of hydrolysis (pH 5), aqueous photolysis, aerobic aquatic metabolism

91-0665 -- submission of anaerobic aquatic metabolism

4. STUDY IDENTIFICATION:

Spare, W.C. Hydrolysis of ¹⁴C-Propanil at pH 5. sponsored by the Propanil Task Force. performed by Agrisearch Incorporated, Frederick, MD. dated 1/16/89. rec'd EPA 4/18/89 under MRID# 410666-01.

Kesterson, A.L., Lawrence, B., Marsh, J.D., King, D.L., and Lawrence, L.J. Aqueous Photolysis of ¹⁴C Propanil in Natural Sunlight. sponsored by the Propanil Task Force. performed by Pharmacology & Toxicology Research Laboratory, Lexington, KY. dated 4/10/89. rec'd EPA 4/25/89 under MRID# 410707-01

Spare, W.C. Anaerobic Aquatic Metabolism of Propanil. sponsored by the Propanil Task Force. performed by Agrisearch Incorporated, Frederick, MD. dated 5/2/91. rec'd EPA 5/14/91 under MRID# 418726-01.

Spare, W.C. Aerobic Aquatic Metabolism of Propanil. sponsored by the Propanil Task Force. performed by Agrisearch Incorporated, Frederick, MD. dated 4/8/91. rec'd EPA 4/19/91 under MRID# 418487-01.

5. REVIEWED BY:

Typed Name: E. Brinson Conerly-Perks
Title: Chemist, Review Section 3
Organization: EFGWB/EFED/OPP

E. B. Conerly-Perks
11/7/91

6. APPROVED BY:

Typed Name: Akiva Abramovitch
Title: Head, Review Section 3
Organization: EFGWB/EFED/OPP

Akiva Abramovitch
JAN 7 1992

7. CONCLUSIONS:

hydrolysis

- 1) This study completes the fulfillment of the requirement for hydrolysis data. Propanil has previously been shown to be stable at pHs 7 and 9.
- 2) Propanil is stable at pH 5. No significant hydrolysis was observed over the 30 day experimental period.

Data
1

aqueous photolysis

- 1) The study, although seriously flawed, is marginally acceptable to fulfill the requirement for aqueous photolysis data.
- 2) It provides the information that unsensitized aqueous photolysis will not be an important degradative pathway for Propanil.
- 3) If photolysis occurred at a faster rate, this study would be unacceptable. However, in this case, even if the study were repeated, the estimated photolysis half-life of Propanil and its characterization as relatively stable to light would not be likely to change significantly.
- 4) The level of temperature control claimed by the applicant ($\pm 0.3^\circ$) cannot be verified from the data in the submission. The apparent fluctuation in temperature is far greater than $\pm 0.3^\circ$ -- the reported difference between minimum and maximum temperature during a single day was generally at least 5° , and on several days was more than 10° . This might be sufficient to affect the rate of the reaction. As a rule-of-thumb, the rate of a reaction would be expected to double if the temperature rises ten degrees. However, we note that only a summary of the available temperature data is given, and more complete details might justify the applicant's claim.
- 5) The extrapolated value for the half-life is well beyond the period of the experiment, and therefore not necessarily very accurate.

anaerobic aquatic metabolism

- 1) The study does not fulfill the requirement for anaerobic aquatic metabolism data at this time. It will become acceptable when certain inconsistencies in the description of extraction of bound material are resolved.
- 2) It provides the supplementary information that anaerobic metabolism in "active" water and sediment is rapid with a half-life of 2 to 3 days under experimental conditions.

aerobic aquatic metabolism

- 1) The study does not fulfill the requirement for aerobic aquatic metabolism data at this time. It will become acceptable when certain inconsistencies are satisfactorily explained:
 - the behavior of 3,4-dichloroaniline in sterile vs vital systems
 - the description of extraction of bound material
- 2) It provides the supplementary information that aerobic metabolism in "active" water and sediment is rapid with a half-life of 2 days under experimental conditions.

8. RECOMMENDATIONS:

- 1) hydrolysis -- The applicant should be informed that this data requirement is fully satisfied.
- 2) aqueous photolysis -- The applicant must provide a discussion explaining the basis for their statement regarding temperature control.
- 3) anaerobic aquatic metabolism -- The applicant must provide a revised description of the extraction of bound material (on page 17 of the current submission), since the actual procedure used cannot be discerned from the material submitted. In addition to a narrative description, a flow chart or diagram will also be appreciated.

4) aerobic aquatic metabolism

The applicant must provide at least a tentative explanation of the inconsistency in the behavior of 3,4-dichloroaniline in the sterile and vital systems. The applicant must also provide a revised description of the extraction of bound material (on page 16 of the current submission), since the actual procedure used cannot be discerned from the material submitted. In addition to a narrative description, a flow chart or diagram will also be appreciated.

9. BACKGROUND:

ENVIRONMENTAL FATE ASSESSMENT

The data base for Propanil is incomplete at this time, and therefore only very limited assessment can be made of its expected behaviour in the environment. Propanil is stable to hydrolysis at pH 5, 7, and 9 in the laboratory, and, based on a marginally acceptable study, is stable to unsensitized aqueous photolysis. Based on partially acceptable studies, it is rapidly metabolized under aerobic or anaerobic conditions in a water/sediment milieu, and undergoes hydrolysis at a moderate rate in the same water/sediment system. These same studies indicate that degradates from metabolism prefer to associate with the soil phase rather than the aqueous phase, i.e. they become more immobile with time. Based on a partially acceptable study, Propanil metabolizes rapidly in aerobic soil with a half-life of 0.5 days. Other environmental fate data, which include leaching, anaerobic soil metabolism, aquatic metabolism, and field dissipation, are yet to be submitted.

GROUND WATER ASSESSMENT

Due to its rapid metabolism in a water/soil matrix, Propanil might not be likely to persist in ground water.

SURFACE WATER ASSESSMENT

Due to its rapid metabolism in a water soil/matrix, Propanil might not be likely to persist in surface water.

DATA BASE ASSESSMENT

Data requirements for aquatic food use (i.e. rice) and their status:

hydrolysis -- stable at pH 5, 7, and 9. The pH 5 study is discussed in this review

photolysis in water -- fulfilled, discussed in this review. The study provides the marginally acceptable information that Propanil is stable for 30 days to unsensitized photolysis in water. Note that the extrapolated value for the half-life (103.3 days) is well beyond the experimental period, and therefore not necessarily accurate.

anaerobic aquatic metabolism -- partially fulfilled, discussed in this review. The study provides supplemental information that Propanil is rapidly metabolized under anaerobic conditions ($t_1/2$ = 2-3 days)

aerobic aquatic metabolism -- partially fulfilled, discussed in this review. The study provides supplemental information that Propanil is rapidly metabolized under aerobic conditions ($t_1/2$ = 2 days)

leaching/adsorption/desorption -- pending, also required for terrestrial crop use as noted above; to be submitted by the Propanil Task Force

aquatic field dissipation -- pending, to be submitted by the Propanil Task Force

long term field dissipation -- conditionally required, if the conventional short term field dissipation study so indicates

confined accumulation on rotational crops -- pending, will be submitted by the Propanil Task Force

field accumulation on rotational crops -- requirement reserved pending results of confined study, also required for terrestrial uses

confined accumulation on irrigated rotational crops -- pending

fish bioaccumulation -- waiver recommended due to low k_{ow} and applicant's affirmation of low accumulation in fathead minnows

According to the 1987 Registration standard, 95% of the manufactured product is used on rice. The Propanil Task Force does not intend to submit data to support the terrestrial food uses (i.e. the 5% which is not rice). The additional studies required for registration on terrestrial crops include:

photodegradation on soil -- NOT FULFILLED -- will not be submitted by the Propanil Task Force

aerobic soil metabolism -- partially fulfilled, supplemental information provided by MRID 415387-01 (EBC 12/3/90) which indicated a short half-life (0.5 days). The primary degradate was DCA, with a half-life of ca. 30 days.

anaerobic soil metabolism -- partially fulfilled by the anaerobic aquatic metabolism study discussed in this review. The study provides the supplemental information that Propanil is rapidly metabolized under anaerobic conditions (t_1 = 2-3 days).

terrestrial field dissipation -- NOT FULFILLED -- will not be submitted by the Propanil Task Force

accumulation in confined rotational crops -- NOT FULFILLED -- will be submitted by the Propanil Task Force for rice

accumulation in field rotational crops -- conditionally required, if the confined study indicates uptake of residues of concern

Because of informal reports that Propanil applied to rice subsequently reached and damaged non-target crops, especially prune trees, EFGWB also requires the following studies, which are not usually imposed for aquatic uses:

lab volatility

spray drift -- EFGWB believes some studies have already been done.

If this is the case, they should be submitted and evaluated before additional work is initiated

downwind monitoring of deposition on other crops -- for this special study, a protocol must be submitted and approved in advance. It should be designed to identify formulation type(s), if any, which inhibit or enhance migration of Propanil from the target crop.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: See individual DER
11. COMPLETION OF ONE-LINER: attached
12. CBI APPENDIX: attached to DERs

bcp

Data 4