



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

SEP 14 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Response to the Propanil Reregistration Standard:
Residue Chemistry (MRID # 42301001, CBRS # 9876,
Barcode: D178275).

FROM: R. B. Perfetti Ph.D., Chemist *R B Perfetti*
Reregistration Section 1
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: P. Deschamp, Acting Section Head *P Deschamp*
Reregistration Section 1
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Lois Rossi, Chief
Reregistration Branch
Special Review & Reregistration Division (H7508W)

and

E. Saito, Acting Chief
Chemical Coordination Branch
Health Effects Division (H7509C)

Attached is a review of residue chemistry data submitted in response to the propanil Reregistration Standard. This review was completed by Acurex Corporation under supervision of CBRS, HED. It has undergone secondary review in the branch and has been revised to reflect Agency policies.

A revised Tentative Residue Chemistry Summary sheet is included.

If you need additional input please advise.

Attachment 1: Propanil Residue Chemistry Data Review.

cc (With Attachment 1): RBP, Propanil Reregistration Standard File, Propanil Subject File, RF, Circ. and Acurex.

396

PROPANIL
(Chemical Code 028201)
(CBRS No. 9876; DP Barcode D178275)

TASK 3

**Registrant's Response
to Residue Chemistry Data
Requirements**

August 21, 1992

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Environmental Corporation
Eastern Region Operations
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709

397

2

PROPANIL

(Chemical Code 028201)

(CBRS No. 9876; DP Barcode D178275)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY REQUIREMENTS

Task 3

BACKGROUND

The Propanil Guidance Document dated 12/87 required data depicting the magnitude of residue in crayfish resulting from propanil (3',4'-dichloro-propionanilide) EC formulations applied to rice at 6 lb ai/A and harvested in early December following a mid-July treatment. The Guidance Document also stated that the studies could be conducted in conjunction with those required for rice grain.

In response to the Guidance Document, the Propanil Task Force submitted protocols for magnitude of residue studies in or on crayfish. These protocols were reviewed by H. Fonouni (CBRS No. 6442; 4/18/90) who noted that the maximum seasonal application rate for rice is 8 lb ai/A and that the Task Force should employ this rate instead of the proposed 4 lb ai/A to generate the residue data for crayfish. The registrant subsequently submitted data (1992; MRID 42301001) pertaining to the residues of propanil and its metabolites in or on crayfish from a rice-crayfish polyculture treated with 4 lb ai/gal EC applied at the 4 lb ai/A (0.5x the maximum labeled seasonal rates). Also included is the description of an analytical method for determining propanil and its metabolites in rice and crayfish. These submissions are reviewed here to determine their adequacy in fulfilling outstanding magnitude of residue data requirements. The Conclusions and Recommendations stated in this review pertain only to magnitude of residue data for crayfish.

The qualitative nature of the residue in plants is not adequately understood. Requirements for a wheat metabolism study and additional data from the existing rice metabolism study remain outstanding. The qualitative nature of the residue in crayfish is adequately understood (R. Perfetti, CBRS Nos. 7960 and 8522, 3/23/92), terminal residues in crayfish muscle consist of 3,4-dichloroaniline (DCA) and N-3,4-dichlorophenyl-glucosylamine. Tolerances for residues of propanil in or on raw agricultural commodities are currently expressed in terms of propanil and its metabolites, calculated as propanil (40 CFR §180.274). There is no tolerance for propanil residues in shellfish.

The currently preferred enforcement method for plant and animal commodities is the GC method listed as Method I in PAM Vol II. The method employs base hydrolysis to convert propanil and its metabolites to DCA, which is then quantified.

There is no established Codex MRL for residues of propanil or its metabolites in or on crayfish. Therefore, there is no question with respect to Codex/U.S. tolerance compatibility.

BEST COPY AVAILABLE

398 3

CONCLUSIONS/RECOMMENDATIONS

- 1a. This study does not fulfil the requirements for residue chemistry data on crayfish. Only one application was performed, representing 0.5x the maximum label rate. Harvest was performed one year after treatment, rather than at 7 months. The registrant should conduct a new study reflecting two applications of propanil at 4 lb ai/A each and a 7-month harvest interval, which would be the minimum treatment-to-harvest interval, given April application and November crayfish harvest.
- 1b. The data indicate that base releasable 3,4-DCA, expressed as propanil equivalents, reaches a level of 0.07 ppm in crayfish harvested approximately one year after a single application at 4 lb ai/A to rice paddy water. A tolerance for propanil residues in crayfish should be proposed when the crayfish residue data base is complete (refer to conclusion 1a.).

DETAILED CONSIDERATIONS

Residue Analytical Methods

As part of the submitted crayfish data (1992; MRID 42301001), Wildlife International provided method validation data for the EN-CAS Method No. ENC-9/90 for determination of propanil and its metabolites as base-released DCA in rice commodities and crayfish (Appendix G). This method is based on Method II in PAM, Vol. II, with substantial modifications.

The method was reviewed by the Agency (R. Perfetti, CBRS No. 9589, 6/22/92) and was determined to be adequate, except for calculations used to determine propanil equivalents from N-(3,4-dichlorophenyl)D-glucosylamine (DCA-glucose) equivalents. Those calculations have been corrected in the current submission. The method adequately recovers propanil as base-released DCA in rice commodities and crayfish.

Fortification data supplied as part of the current submission (EN-CAS Project #90-0025, Appendix F) are summarized in Table 1. Control samples were spiked with 3,4 DCA, 3,4-DCA-glucose, and propanil and analyzed with the field samples.

Table 1. Recovery of 3,4-DCA, 3,4-DCA glucose, and propanil from one fortified sample each of crayfish as determined by base hydrolysis to DCA.

Commodity	Fortification compound	Fortification level (ppm)	Percent recovery
Crayfish	3,4-DCA	0.01	88
	3,4-DCA	0.05	91
	3,4-DCA glucose	0.05	60,86
	propanil	0.01	88
	propanil	0.05	96

Storage Stability Data

Wildlife International (1992; MRID 42301001) submitted data regarding crayfish tail meat stored frozen at -23 °C to -27 °C for up to 18 weeks (one of the field samples was analyzed after storage for up to 22 weeks). Storage stability data depicting residues of propanil and DCA-glucose in crayfish tail meat are summarized in Table 2. Recovery values ranged from 74-81% for propanil and 71-81% for DCA-glucose after 18 weeks of storage. These data indicate that residues of propanil and DCA-glucose are stable in crayfish samples stored at -23 °C to -27 °C for up to 18 weeks. A decline in residue levels after storage for 22 weeks is unlikely.

Table 2. Storage stability of propanil and 3,4-DCA in crayfish samples fortified at 0.2 ppm in the laboratory (LA study, MRID 42301001).

Sample Description	Storage Interval	ppm found or percent recovery ^a	
		Propanil	DCA-Glucose
Control	0 weeks	<0.01	<0.01
Fresh fortification	0 weeks	76%,76%	76%,61%
Control	18 weeks	<0.01	<0.01
Fresh fortification	18 weeks	88%,82%	68%,75%
Stored fortification ^b	18 weeks	81%,74%	81%,71%

^aTotal residues expressed as base releasable 3,4-DCA. ^bStored fortified values not corrected for procedural recovery of fresh fortifications.

Magnitude of the Residue in Fish/Shellfish

No tolerances have been established for the residues of propanil and its metabolites, calculated as propanil, in or on crayfish (40 CFR §180.274). The 4 lb/gal EC formulation (EPA Reg. No. 707-109) is registered for ground and aerial application to rice at 3-6 lb ai/A/application, not to exceed 8 lb ai/A/season. Aerial applications are made in a minimum of 10 gal/A and ground applications are to be made in 15 gal/A. There is no minimum interval between applications specified. Normal practices for rice/crayfish polyculture indicate application of herbicide throughout the spring and summer growing season for weed control. Fields are typically drained prior to propanil use and reflooded 12 hours to 5 days after application. Crayfish are harvested throughout winter (Nov-Dec) and during the following spring months using baited traps.

Wildlife International submitted data (1992; MRID 42301001) from tests conducted in LA depicting residues of propanil in or on crayfish. Propanil (4 lb/gal EC) was applied once in April, 1990 aerially at 4 lb ai/A (0.5x the seasonal maximum) to drained rice paddy sites. Applications were made at 10 gal/A. The application rate was applied at two test rice paddy sites (T1 and T2) and one control rice paddy site (C1). Fields were reflooded within 24 hours of application and maintained at flood level until draining at harvest. Crayfish harvest was conducted in the spring of 1991 (March-April) rather than December, 1990 due to insufficient numbers of available crayfish at winter harvest time in the treated paddies. The resulting posttreatment interval was 340 days for paddy T1 and 319 days for paddy T2. The 3,4-DCA crayfish residue data with calculated propanil equivalents are presented in Table 3.

Table 3. Base releasable 3,4-DCA residues (ppm) in crayfish exposed to propanil residues in rice paddy water.

Sample Site	Harvest Date (storage interval, weeks)	Base-releasable DCA residues (ppm) ^a	Propanil equivalents (ppm) ^b
Control, C1	12/14/90 (16)	<0.01, <0.01 (<0.01)	<0.014, <0.014 (<0.014)
Paddy, T1	4/24/91 (22)	0.02, 0.02, 0.05 (0.03)	0.03, 0.03, 0.07 (0.04)
Paddy, T2	3/8/91 (4)	0.01, 0.01, <0.01 (0.01)	0.014, 0.014, <0.014 (<0.014)

^aMean value in parentheses. ^bPropanil equivalent equals ppm DCA times 1.35 (correction for molecular weight difference).

The data indicate that propanil application at 0.5x the maximum seasonal label rate with harvest one year later resulted in residue levels in crayfish of 0.07 ppm. The registrant should perform a new study at the maximum seasonal application rate (8 lb ai/A) in two single spring applications of 4 lb ai/A. Crayfish should be harvested at a typical 7-month harvest interval (winter harvest). After the crayfish residue data base is complete, a

tolerance for propanil residues in crayfish should be proposed by the registrant.

References

Citations for the MRID documents referenced in this review are presented below. Submissions reviewed in this document are indicated by [REDACTED].

[REDACTED]

Agency Memoranda:

CBRS No.: 6442
Subject: Propanil Registration Standard - Magnitude of the Residue in/on Rice, Processed Products of Rice, Irrigation water and Crayfish: Field Study Protocols, dated 2/12/90.
From: H. Fonouni
To: B. Baker and R. Engler
Thru: W. Boodee
Dated: 4/18/90
MRID(s): N/A

CBRS Nos.: 7960 and 8522
Subject: Propanil Task Force: Response to the Propanil Reregistration Standard - Animal Metabolism Studies.
From: R. Perfetti
To: W. Burnam and L. Rossi
Thru: E. Zager
Dated: 3/23/92
MRID(s): 41893901, 441843901, 41849101

CBRS No.: 9589
Subject: Response to the Propanil Reregistration Standard - Residue Data.
From: R. Perfetti
To: W. Burnam and L. Rossi
Thru: E. Zager
Dated: 6/22/92
MRID(s): 42237101, 42237201, 42237301

PROPANIL (CASE No. 226)		
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 9/10/92¹		
REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH CODEX²		
Guideline Number and Topic³	Are data requirements satisfied?	MRID(s)⁴
171-3 Directions for use		
171-4(a) Plant Metabolism	N ^{5,6}	42209200,42209201
171-4(b) Animal Metabolism	N ^{7,8}	41755001,41755301 41848801,41983901
171-4(c) Residue Analytical Methods - Plants	N	
171-4(d) Residue Analytical Methods - Animals	N	
171-4(e) Storage Stability	N	
171-4(k) Crop Field Trials		
171-4(k) Cereal Grains Group		
Barley [see 171-4(l)]	N	
Oats [see 171-4(l)]	N	
Rice [see 171-4(l)]	Y ⁹	42237101, 42237201
Wheat [see 171-4(l)]	N	
171-4(k) Forage, Fodder, and Straw of Cereal Grains		
Barley forage and straw	N	
Oats forage and straw	N	
Rice straw	Y ¹⁰	42237301
Wheat forage and straw		
171-4(l) Processed Food/Feed		
Rice	N	
Wheat	N	
171-4(j) Meat/Milk/Poultry/Eggs	N	
171-4(f) Potable Water	Y	" 42200401,42200501
171-4(g) Fish	N ^{12,13}	42301001, 41448901, 41849101
171-4(h) Irrigated Crops	Y	
171-4(i) Food Handling Establishments	N/A	
171-5 Reduction of Residues	N/A	

¹Registration Standard issued 12/87. No Reregistration Standard Update issued.

² There are no Codex MRL's proposed or established for propanil.

³N/A = Guideline requirement not applicable.

⁴MRIDs that were reviewed in the current submission are designated in shaded type.

⁵ CBRS# 8703, 2/14/92 (C. Olinger): Interim rice metabolism report. Additional information is needed.

⁶CBRS 9528, 4/2/92 (J. Abbotts): Wheat metabolism study. Additional information is needed. Only parent is characterized, representing no more than 13% of the TRR.

⁷ CBRS# 7622, 2/21/92 (C. Olinger): Metabolism in poultry is adequately understood. Additional information on the methodology, a lab validation and a method trial are needed.

⁸ CBRS#'s 7960 and 8522, 3/18/92 (R. Perfetti): Additional information regarding radioactive residues milk and fat are needed in order to upgrade this study.

⁹CBRS # 9589, R. Perfetti, 6/22/92; The data for rice grain is acceptable. However a higher tolerance is needed. Ten ppm would be adequate. When the higher tolerance is established for rice grain, then the food/feed additive tolerances for processed fractions must also be revised.

¹⁰CBRS # 9589, R. Perfetti, 6/22/92; Residue data on rice straw indicate that the established tolerance is adequate. No additional data on straw is needed.

¹¹ CBRS #9541, RBP (8/28/92). Provided the Registrant amends the propanil label to prohibit the discharge of rice paddy water within 60 days of the last application there is no need for an MCL for propanil residues in water or for tolerances in irrigated crops. A 14 day interval between applications should be specified on the label. The current label directions for ground applications should be deleted.

¹² CBRS#'s 7960 and 8522, 3/18/92 (R. Perfetti): The metabolism of propanil in crayfish is adequately understood. Magnitude of the residue data in fish and shellfish are required.

¹³ RBP, CBRS # 9876, 9/10/92. This study does not fulfil the requirements for residue chemistry data on crayfish. Only one application was performed, representing 0.5x the maximum label rate. Harvest was performed one year after treatment, rather than at 7 months. The registrant should conduct a new study reflecting two applications of propanil at 4 lb ai/A each and a 7-month harvest interval, which would be the minimum treatment-to-harvest interval, given April application and November crayfish harvest.

The data indicate that base releasable 3,4-DCA, expressed as propanil equivalents, reaches a level of 0.07 ppm in crayfish harvested approximately one year after a single application at 4 lb ai/A to rice paddy water. A tolerance for propanil residues in crayfish should be proposed when the crayfish residue data base is complete.

cc: RBP; Propanil Reregistration Standard File; L. Rossi, SRRD.