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

NOV 6 1992

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Reregistration of Propanil: Rice Processing Study; Chemical No. 28201;  
Branch No. 10362; DP Barcode No.: D181471; MRID No. 42417401

FROM: Christine L. Olinger, Chemist *Christine Olinger*  
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THRU: Paula A. Deschamp, Acting Section Head *PA Deschamp*  
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TO: Lois Rossi, Chief  
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Special Review and Reregistration Division (H7508C)

Attached is the review of a propanil rice processing study submitted by the Propanil Task Force. This information was reviewed by Acurex Corporation under supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies. A tentative residue chemistry status form is attached.

This study is adequate and the registrant must revise the existing feed additive tolerances once the nature of the residue has been adequately delineated. There is an outstanding requirement for a rice grain dust processing study.

If you need additional input please advise.

Attachment 1: Review of Propanil Residue Chemistry Data

cc: (with Attachment 1): CLOlinger (CBRS), Reg. Std. File, SF, Acurex, Circu., RF

ATTACHMENT I

**PROPANIL**  
**(Chemical Code 028201)**  
**(CBRS No. 10362; DP Barcode D181471)**

**TASK 3**

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

October 16, 1992

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency  
Arlington, VA 22202

Submitted by:

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Eastern Regional Operations  
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## PROPANIL

(Chemical Code 028201)

(CBRS No. 10362; DP Barcode D181471)

### REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY REQUIREMENTS

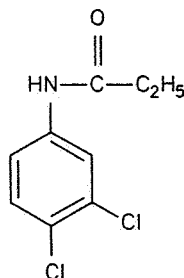
#### Task 3

#### BACKGROUND

The Propanil Guidance Document dated 12/87 required data depicting propanil residues in or on rice grain dust obtained from rough rice grain bearing measurable weathered residues. No data were requested for processed rice grain commodities. The Propanil Residue Chemistry Chapter dated 8/87 previously reviewed processing data from rice grain bearing propanil residues and concluded that feed additive tolerances representing a 13x concentration in rice bran and a 5x concentration in rice hulls were necessary. Subsequently, the Propanil Task Force submitted data (1992; MRID 42417401) from a rice grain processing study. This submission is reviewed here to determine its adequacy in fulfilling residue chemistry data requirements. The Conclusions and Recommendations stated in this review pertain only to the magnitude of propanil residues in processed rice commodities.

The nature of the residue in plants and animals is not adequately understood. Reviews of metabolism studies on poultry (C. Olinger, CBRS No. 7622, 2/21/92), and crayfish (R. Perfetti, CBRS Nos. 7960 and 8522, 3/23/92) have deemed these studies adequate; however, additional data requested from the rice, wheat, and ruminant metabolism studies remain outstanding.

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). Feed additive tolerances of 10 ppm have also been established for propanil and its metabolites in rice bran, hulls, polishings, and mill fractions (40 CFR §186.1875).



Propanil

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 3,4-dichloroaniline (DCA), which is then quantified.

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

## CONCLUSIONS

- 1a. Data in the current submission indicate that propanil residues concentrated in rice bran and hulls processed from treated grain by a maximum of 4.6x and 3.4x, respectively. However, previous adequate rice processing studies indicated concentration factors of 13x and 5x for rice bran and hulls, respectively. Unless the registrant can provide adequate justification for disregarding the older data, feed additive tolerances will have to be proposed based on concentration factors of 13x for bran and 5x for hulls.
- 1b. Previously submitted data indicate that the established 2 ppm tolerance for rice grain is too low (MRIDs 42237101, 42237201, and 42237301, reviewed by R. Perfetti, CBRS No. 9589, 6/22/92). Residues were detected in rice grain at levels up to 2.7 ppm from treatment at 1x the maximum seasonal rate (two applications at 4 lb ai/A each) and up to 9.18 ppm from treatment at 1x the maximum single application rate (6 lb ai/A). After the nature of the residue in rice has been adequately described, the registrant must propose a revised tolerance for propanil residues in or on rough rice grain. When the revised tolerance is proposed for the grain, the registrant must also propose revised feed additive tolerances for rice bran and hulls using the appropriate concentration factors.
2. No magnitude of residue data for propanil residues in or on rice grain dust were provided in the current submission. Because propanil residues concentrate in rice bran and hulls, propanil residues are also likely to concentrate in grain dust. Therefore, data pertaining to propanil residues in or on rice grain dust remain outstanding.

Note to SRRD: Feed additive tolerances for propanil residues in rice polishings and rice mill fractions (40 CFR §186.1875) are not appropriate and should be revoked.

## DETAILED CONSIDERATIONS

### Residue Analytical Methods

The Propanil Task Force submitted method descriptions along with the residue data (1992; MRID 42417401). Propanil residues in or on rice commodities were determined by a GC method that uses a nitrogen-phosphorus detector (NPD), EN-CAS Method No. ENC-9/90. The method is based on Method II in PAM, Vol. II (Sec. 180.274), with substantial modifications. In method ENC-9/90, residues of propanil and its metabolites are determined as base-releasable DCA. Residues of propanil are base hydrolyzed to DCA, steam distilled into hexane, and cleaned-up using a silica gel column prior to analysis by GC-NPD.

Method validation data were provided for rice grain, polished rice grain, hulls, and bran. These data were previously reviewed (R. Perfetti, CBRS No. 9589, 6/22/92) and indicate that method ENC-9/90 adequately recovers propanil as base-released DCA from rough rice grain and processed rice commodities. Method recoveries were 70-126% from rough and polished rice grain fortified with propanil at 0.01-0.25 ppm, 60-122% from rice bran fortified at 0.02-0.25 ppm, and 80-113% from rice hulls fortified at 0.05 and 0.25 ppm. Detection limits are 0.01 ppm for rough and polished rice grain, 0.02 ppm for rice bran, and 0.05 ppm for rice hulls.

In addition to the previously reviewed validation data, the current submission included concurrent method recoveries for DCA and/or propanil from control samples of rough rice grain and processed commodities fortified at levels approximating the actual residue levels in the treated samples. These data are summarized in Table 1 and indicate that method ENC-9/90 adequately recovers propanil residues from rice commodities.

Table 1. Concurrent method recoveries of propanil and DCA from samples of rough rice grain and processed rice commodities.

Analyte	Fortification (ppm)	Percent Recovery				
		Rough rice grain	Hulls	Bran	Brown Rice	Polished Rice
DCA	0.01	- <sup>a</sup>	-	-	-	94
	0.1	82	88	91	65, 94	83, 97
	1.0	75	70	79	90, 65	76
	5.0	75, 69	80	108	-	-
	10	81	87	-	-	-
	20	-	-	99	-	-
Propanil	0.1	-	-	-	105	108
	1.0	-	-	-	85	86
	5	96	100	110	-	-
	10	92	94	-	-	-
	20	-	-	101	-	-

<sup>a</sup>Not applicable.

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### Storage Stability Data

Prior to processing, rough rice grain samples harvested from the AR, LA, and TX test sites were stored frozen at an unspecified temperature for 56, 112, and 480 days, respectively. After processing, rough rice grain and the processed fractions from AR, LA, and TX were stored at  $\leq -23$  °C for an additional 227, 229, and 23-83 days, respectively, prior to extraction and analysis. The total storage interval for rough rice grain samples from AR, LA and TX were 283, 341, and 503-563 days, respectively.

Storage stability data for rice grain were reviewed in the 8/87 Propanil Residue Chemistry Chapter and indicated that propanil residues in or on rice grain are stable in frozen storage for up to 525 days. These data indicate that propanil residues are stable in the samples stored for the intervals reflected in the current submission.

### Magnitude of the Residue in Plants

Rice Processed Commodities. A tolerance of 2 ppm has been established for the residues of propanil and its metabolites, calculated as propanil, in or on rice grain (40 CFR §180.274). In addition, feed additive tolerances of 10 ppm have been established for propanil and its metabolites in rice bran, hulls, polishings, and mill fractions (40 CFR §186.1875). A review (H. Fonouni; CBRS No. 6442; 4/18/90) of protocols for propanil residue studies on rice indicates that the Propanil Task Force is currently supporting maximum single and seasonal application rates of 6 and 8 lb ai/A, respectively, with the maximum seasonal rate applied as two 4 lb ai/A applications.

The 8/87 Propanil Residue Chemistry Chapter reviewed several adequate rice processing studies (1966-67, MRIDs 00035687 and 00035688; 1969, MRID 00035576; 1970, MRID 00052347). Maximum concentration factors from three separate studies were 11.8x, 12.8x, and 7.1x for rice bran and were 4.7x, 4.4x and 2.6x for rice hulls. The Agency concluded that feed additive tolerances representing a 13x concentration in rice bran and a 5x concentration in rice hulls were necessary. In addition, data were required depicting propanil residues in rice grain dust.

The Propanil Task Force submitted data (1992; MRID 42417401) depicting the concentration of propanil residues in commodities processed from rough rice grain bearing measurable propanil residues. Rough rice grain samples used for the processing study were obtained from four residue tests conducted in AR(1), LA(1), and TX(2); these were among the tests previously reviewed for rice grain residues (R. Perfetti; CBRS No. 9589, 6/22/92). Rice plants received aerial broadcast applications of propanil at 4+4 lb ai/A (1x the maximum seasonal rate; three tests) or 6 lb ai/A (1x the single application rate; one test). Samples of rough rice grain were frozen after harvest. Prior to processing, samples of rice from the AR, LA, and TX tests were stored frozen at an unspecified temperature for 56, 112, and 480 days, respectively. Rough rice grain samples were processed into hulls, brown rice, bran, and polished rice using simulated commercial practices.

Propanil residues in or on rough rice grain and in processed fractions were determined using method ENC-9/90, a GC/NPD method that determines propanil residues as base-released DCA. A single control and treated sample of each sample matrix was extracted and analyzed from each test. Residues of propanil were determined as base-released DCA and expressed in propanil equivalents. Residues in or on rough rice grain and in processed rice commodities are reported in Table 2. Apparent residues of propanil were 0.01-0.07 ppm in or on three control samples of rough rice grain; <0.07-0.2 ppm in three control samples of rice hulls; 0.03-0.18 ppm in three control samples of rice bran; <0.01-0.03 ppm in three control samples of brown rice; and ≤0.01 ppm in three control samples of polished rice. Propanil residues did not concentrate in brown and polished rice and the maximum concentration factors for rice bran and hulls were 4.6x and 3.4x, respectively.

Table 2. Residues of propanil and its metabolites, determined as base-released DCA, in or on rice grain and processed rice commodities.

Test site/ Rate	Residues in Propanil Equivalents (ppm)				
	Rough Rice Grain	Rice Hulls	Rice Bran	Brown Rice <sup>b</sup>	Polished Rice Grain <sup>b</sup>
<u>Arkansas</u>					
4+4 lb ai/A	0.04	0.08 (2x) <sup>a</sup>	0.11 (2.8x)	0.03	<0.01
<u>Louisiana</u>					
4+4 lb ai/A	0.11	0.37 (3.4x)	0.41 (3.7x)	0.08	0.03
<u>Texas</u>					
4+4 lb ai/A	2.8	5.6 (2x)	9.9 (3.5x)	2.3	0.3
6 lb ai/A	8.4	21 (2.5x)	39 (4.6x)	5.4	1.1

<sup>a</sup>Concentration factor. <sup>b</sup>Propanil residues did not concentrate in brown and polished rice grain.

The available data indicate that feed additive tolerances for rice bran and hulls should be revised and that appropriate concentration factors for determining tolerances in rice bran and hulls are 13x and 5x, respectively. The registrant must propose revised feed additive tolerances for bran and hulls when an appropriate tolerance for rough rice grain has been determined. The recent review (R. Perfetti, CBRS No. 9589, 6/22/92) of propanil residue data for rough rice grain indicates that 10 ppm is an appropriate tolerance for rough rice grain harvested at 60 days posttreatment. However, outstanding data on the nature of the propanil residue in rice are required before a revision of the rough rice grain tolerance will be considered.



## References

Citations for the MRID documents referenced in this review are presented below. Submissions reviewed in this document are indicated by shaded type.

- 00035576 Monsanto Company (1969) Summary of Residue Findings: [Rogue]. (Unpublished study received Sep 18, 1971 under 1F1036; CDL: 091920-A)
- 00035687 Mueller, K.E.; Cherry, W.F.; Smith, L.G.; et al. (1966) Stam Residues on Rough Rice. (Unpublished study including Research Report No. 57-24; received Jun 11, 1970 under 0F0932; prepared in cooperation with Univ. of Arkansas, Agricultural Extension Service, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 091588-F)
- 00035688 Cherry, W.F.; Johnson, W.H.; Owens, F.C.; et al. (1967) [Residues of Stam F-34 on Rice]. (Unpublished study received Jun 11, 1970 under 0F0932; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091589-A)
- 00052347 Henshall, A.; Lauer, R.; Beasley, R.; et al. (1970) Final Report on Rogue Residues: Identification and Analysis--Part VI: Residue Method Development Studies and the Determination of Recoverable 3,4-Dichloroaniline in Field-Treated Rice, Meat, Milk, and Eggs: Agricultural Research and Development Report No. 184. (Unpublished study received Sep 19, 1971 under 1F1036; submitted by Monsanto Co., Washington, D.C.; CDL:091921-B)
- 42237101 Young, D.; Palmer, D.; Johnson, G.; et al. (1992) Magnitude of the Residues of Propanil in or on Rough Rice Grain Treated with Propanil 4 EC at 6 lb ai/Acre: Lab Project Number: 271-107. Unpublished study prepared by Wildlife International Ltd. and EN-CAS Analytical Labs. 430 p.
- 42237201 Young, D.; Palmer, D.; Johnson, G.; et al. (1992) Magnitude of the Residues of Propanil in or on Rough Rice Grain Treated with Propanil 4 EC at 4 lb ai/Acre: Lab Project Number: 271-105. Unpublished study prepared by Wildlife International Ltd. and EN-CAS Analytical Labs. 438 p.
- 42237301 Young, D.; Palmer, D.; Johnson, G.; et al. (1992) Magnitude of the Residues of Propanil in or on Rough Rice Grain Treated with Propanil 4 EC at 4 lb + 4 lb ai/Acre: Lab Project Number: 271-106. Unpublished study prepared by Wildlife International Ltd. and EN-CAS Analytical Labs. 444 p.

42417401 Young, D.; Palmer, D.; Johnson, G; et al. (1992) Magnitude of the Residues of Propanil in or on the Processed Products of Rough Rice Grain Treated with Propanil 4 EC at 4 lb + 4 lb ai/Acre and 6 lb ai/Acre: Lab Project Number: 271-110. Unpublished study prepared by Wildlife International Ltd., EN-CAS Analytical Labs, and South Texas Ag Research, Inc. 386 p.

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.  
From: H. Fonouni  
To: B. Baker and R. Engler  
Dated 4/18/90  
MRID(s) N/A

CBRS No. 7622  
Subject: Propanil: Propanil Task Force Response to the Registration Standard: Residue Chemistry Data.  
From: C. Olinger  
To: L. Rossi  
Dated 2/21/92  
MRID(s) 41754401, 41755301, and 41755001

CBRS Nos. 7960 and 8522  
Subject: Propanil: Propanil Task Force Response to the Registration Standard: Animal Metabolism Studies.  
From: R. Perfetti  
To: W. Burnam and L. Rossi  
Dated 3/23/92  
MRID(s) 41848801, 41983901, and 41848901

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