

US EPA ARCHIVE DOCUMENT



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

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APR 18 1984

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 84-AR-02. Section 18 Emergency Exemption for propiconazole (Tilt) on rice.

FROM: Sami Malak, Chemist *Sami Malak*
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THRU: Charles Trichilo, Chief
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The Arkansas State Plant Board is requesting a Section 18 emergency Exemption allowing use of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl) 4-propyl-1,3-dioxolan-2-yl]methyl]triazole, trade name: Tilt or CGA-64250, for control of various diseases on rice.

A temporary tolerance of 4 ppm for rice grain and 15 ppm for rice hulls was found to be adequate to cover residues of propiconazole, 1-[[2-(2,4-dichlorophenyl) 4-propyl-1,3-dioxolan-2-yl]methyl]triazole and its metabolites containing the 2,4-dichlorobenzoic acid (PP#1G2530, memo of J. Worthington, 1/7/82). The use involved was somewhat different from that proposed here, however, similar to that recently granted to the state of Louisiana (84-LA-04, memo of S. Malak, 4/4/84).

The Arkansas State plant board is requesting 98,438.4 pounds active of propiconazole for aerial or ground treatment of 350,000 acres of rice during the 1984 growing season.

Propiconazole 3.6 E will be applied once using aerial or ground equipment while fields are flooded as a foliar spray at 8-10 fld oz act/A, equivalent to 0.22-0.28 lb act/A, in 5-10 gallons of water at first internode elongation.

The following restriction is imposed: Do not apply when rice panicles (heads) have emerged. The restrictions as written may be confusing. For additional assurance and consistency with other Sec. 18 exemption, a PHI of 50 days should be imposed on this use.

The metabolism of propiconazole in plants (wheat, barley, grapes and peanuts) was discussed in connection with PP#1G2530 (memo of J. Worthington, 1/7/82). It was concluded that propiconazole per se and its metabolites containing the 2,4-dichlorobenzoic acid are the principal residues of concern.

From the data submitted in connection with 84-LA-04 (acc. #252458), we concluded that the residue of concern in plants to be propiconazole, its metabolites convertible to 2,4-dichlorobenzoic acid and 1,2,4-triazole and its conjugates.

The metabolism of propiconazole in the goat was discussed in connection with PP#1G2530 (memo of J. Worthington, 1/7/82). For the purpose of this Section 18 exemption we consider the residue of concern in milk and animal tissues to be propiconazole, its metabolites that could be converted to 2,4-dichlorobenzoic acid and 1,2,4-triazole and its conjugates.

The analytical methodology for propiconazole per se in plants, including rice, was presented under report #AG354 and discussed in connection with PP#1G2530 (memo of J. Worthington, 1/7/82). The method is also suited for determination of propiconazole per se in animals.

A modified procedure that converts propiconazole residues to 2,4-dichlorobenzoic acid was discussed in connection with PP# 1G2530. Recovery and control values in rice are available. Method sensitivity for rice grain was 0.05 ppm and that for rice straw was 0.1 ppm. The method was found adequate to enforce tolerances for rice.

The analytical methodology for residue determination of propiconazole in animals was presented in connection with 84-LA-04, report #AG-359, acc. #252548. In this method, residues of propiconazole is converted to and determined as the 2,4-dichlorobenzoic acid in milk, eggs and animal tissues. The limit of detection is 0.05 ppm for eggs and other tissues, except liver.

For the purpose of this Section 18 emergency exemption, we conclude that the analytical methodologies determine the parent, propiconazole per se, and its phenolic metabolites which are converted to the 2,4-dichlorobenzoic acid moieties. The available methodology does not determine 1,2,4-triazole or its conjugates

Residue Data

Rice

Based on studies submitted in connection with 84-LA-04, we estimated that residues of propiconazole and its metabolites convertible to 2,4-dichlorobenzoic acid will not exceed 0.05 ppm in rice grain reflecting 0.28 lb act/A (1X) and 53-day PHI. Elsewhere we are recommending an inposition of a 50 day PHI. These data, however, did not permit us to estimate the levels of residues of 1,2,4-triazole and its conjugates in rice grain or its fractions.

Straw

Data submitted in connection with 84-LA-04 reflect four field trials from Arkansas, Louisiana and Mississippi in which propiconazole was applied either twice: at internode elongation followed by a second application at booting using 0.169 lb act/A (0.6X) or at 0.28 lb act/A (1X); or once at internode elongation using 0.28 lb act/A (1X). One test plot received 2X dosage at internode elongation. Results showed detectable propiconazole residues in the range of 0.05-2.08 ppm reflecting 0.6X-2X dosage and 53-69 day PHI's. The highest level of 2.08 ppm reflects 0.6X application rate and 57-day PHI. The next highest level reflects 1X application rate and 69-day PHI. These data demonstrate that propiconazole and its metabolites convertible to 2,4-dichlorobenzoic acid will not exceed 3 ppm in/on rice straw at a 50-day PHI.

Rice Milled Fractions

No concentration of residues of priconazole and its metabolites convertible to 2,4-dichlorobenzoic acid was observed in rice hulls, unpolished grain, polished grain and rice bran following treatments at internode elongation at 0.28 lb act/A (1X); at internode elongation at 0.56 lb act/A (2X); or at internode elongation at 0.28 lb act/A followed by a boot stage application at 0.28 lb act/A (1X). Concentration of residues in rice milling fractions was observed at exaggerated application rates and from applications at the heading stage.

Based on these studies we concluded that residues of propionazole and its metabolites convertible to 2,4-dichlorobenzoic acid will not exceed 0.05 ppm in or on rice hulls, polished rice and other milled rice products as a result of the proposed use, provided a 50 day PHI is imposed on this use.

Meat, Milk, Poultry and Eggs

A feeding study in dairy cows was discussed in connection with 84-LA-04 (memo of S. Malak, 4/4/84). In this study, four groups of 3 lactating holstein cows, each was fed diets containing propiconazole at 0, 15,75 and 150 ppm for up to 28 days.

Test results showed no parent (propiconazole per se) residues in milk sample (<0.01 ppm) and tissue (<0.05 ppm) at all feeding levels except liver and one fat sample. In the liver, residues of propiconazole per se were quantitated at 0.14, 0.34 and 0.66 ppm reflecting 15, 75 and 150 ppm feeding levels, respectively. In one fat sample, residues of propiconazole per se was determined at 0.08 ppm, only at the highest feeding level of 150 ppm. No residues were found in the milk (<0.01 ppm) at the 15 ppm feeding level. The maximum residues were 0.08 and 0.11 ppm, reflecting higher feeding levels of 75 and 150 ppm, respectively. No residues were found in the fat and tissue, except liver and kidney, at the lower feeding level of 15 ppm; whereas, at the higher feeding levels residues were 0.08-0.23 ppm at the 75 ppm feeding level and 0.13-0.26 ppm at the 150 ppm feeding level. In the kidney, residues were 0.63, 4.7 and 6.5 ppm, reflecting 15, 75 and 150 ppm feeding levels, respectively. Similarly, in the liver, propiconazole residues were determined at 0.81, 4.3 and 5.6 ppm, reflecting 15, 75 and 150 ppm feeding levels, respectively.

A feeding study in laying hens was also included and discussed in connection with 84-LA-04 (memo of Sami Malak, 4/4/84). In this study 90 mature white leghorn hens were divided into four groups and administered a diet containing propiconazole at 0, 7.5, 37.5 and 75 ppm for 28 days.

Test results showed no parent, propiconazole per se, residues were detected in the eggs or tissues (<0.05 ppm), nor in the liver (<0.1 ppm) of poultry at all dosing levels. No propiconazole residues were detected in the eggs or tissues (<0.05 ppm), nor in the liver of poultry (<0.1 ppm) at the lower dosing level of 7.5 ppm. However, at the higher dosing levels of 37.5 and 75 ppm, propiconazole residues were quantitated at 0.18 and 0.37 ppm for eggs, 0.05 and 0.11 ppm for all tissues, except liver, and 0.16 ppm and 0.47 ppm for the liver of poultry, reflecting dosing levels of 37.5 and 75 ppm, respectively.

The feed items involved in this Section 18 are rice grain with hulls, rice straw and milled fractions of rice. Based on the levels of these items in livestock diets and the estimated tolerances in them, the maximum dietary burden was calculated at <0.35 ppm for cattle (rice grain and milled by-products at 0.05 ppm and 25% in the diet for each, and rice straw at 3.0 ppm and 10% in the diet); and at 0.04 ppm for poultry (rice grain and milled rice fraction at 0.05 ppm and 25% in the diet for each). Accordingly, we estimate that secondary residues of propiconazole and its metabolites convertible to 2,4-dichlorobenzoic acid will not exceed 0.05 ppm in milk, eggs and the meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep as a result of this use.

The available data do not permit us to estimate the levels of secondary residues of 1,2,4-triazole and its conjugates in meat, milk, poultry and eggs from this use.

Conclusions

1. For the purpose of this Section 18 exemption we consider the residues of concern in plants and animals to be propiconazole, its metabolites convertible to 2,4-dichlorobenzoic acid and 1,2,4-triazole and its conjugates.
- 2a. Provided a 50 day PHI is imposed, we can conclude that residues of propiconazole and its metabolites convertible to 2,4-dichlorobenzoic acid will not exceed 0.05 ppm in or on rice grain, rice hulls polished rice and rice milled products.
- 2b. Provided that a 50 day PHI is imposed, we can conclude that residues of propiconazole and its metabolites convertible to 2,4-dichlorobenzoic acid will not exceed 3 ppm in or on rice straw.
- 2c. Provided a 50 day PHI is imposed, we can conclude that secondary residues of propiconazole and its metabolites convertible to 2,4-dichlorobenzoic acid will not exceed 0.05 ppm in milk, eggs and the meat, fat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep as a result of this use.
- 2d. The available residue data do not permit us to estimate the levels of residues of 1,2,4-triazole and its conjugates in rice grain and its fractions and in meat, milk poultry and eggs. We defer to TOX regarding their concern over those residue.
3. The Methods AG-356, PP#1G2530 for rice and its fractions and AG-359 Accession number 252548 for milk, eggs and animal tissues may be used for enforcement of this Section 18 exemption. The methods determine propiconazole and its metabolites convertible to 2,4-dichlorobenzoic acid; they do not determine 1,2,4-triazole or its conjugates.

Recommendation

TOX considerations permitting and provided a 50 day PHI is imposed (Note Conclusion 2d) we have no objections to the issuance of this Section 18 exemption. An agreement should be made with FDA regarding the legal status of the treated rice in commerce.

TS-769:RCB:S.Malak:vg:CM#2:RM180:X77377:4/18/84
cc: R.F., Circu., Propiconazole, S.F., Section 18
RDI: E. Zager, 4/16/84; R. Schmitt, 4/16/84