

US EPA ARCHIVE DOCUMENT

Amend. Reg. File

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

MAY 5 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: LA-920004 METALAXYL (RIDOMIL®) - SPECIAL LOCAL NEED [24(c)]
REGISTRATION AND AMENDED USE REGISTRATION FOR EPA REGISTRATION
NUMBER 100-607 (RIDOMIL® 2E FUNGICIDE) ON WATER SEEDED RICE.
Review of Amendment with New Magnitude of the Residue Data -
Crop Field Trials.
(MRID# 422598-05) [CBTS#s 11708 and 11709]{DP Barcode#s
D189772 and D189764}

From: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support
Health Effects Division (H-7509C) *Francis D. Griffith*

Thru: Robert S. Quick, Section Head
Tolerance Petition Section I
Chemistry Branch I - Tolerance Support
Health Effects Division (H-7509C) *mjn (for RSQ)*

To: Julie Fairfax/Susan Lewis, PM Team 21
Fungicide-Herbicide Branch
Registration Division (H-7505C)

BACKGROUND

The Louisiana Department of Agriculture and Forestry, in a letter dated February 11, 1993, requests the Agency reinstate SLN No. LA 92-0004 for Ridomil® 2E under Section [24(c)]. The [24(c)] registration for use of Ridomil® on rice in Louisiana initially did not receive a favorable recommendation due to deficiencies in magnitude of the residue crop field trials and processing studies (see memorandum dated June 12, 1992, by F.D. Griffith, Jr.). Attached to the letter is a revised label for a SLN registration of a metalaxyl use on water seeded rice in Louisiana. Also the Agency is requested to include in our review and comment on the new magnitude of the residue data for crop field trials presented by the registrant supporting an at-planting use on water seeded rice. If the Agency has concerns relating to potential over tolerance residues in rice resulting from a dual application of metalaxyl on treated rice seed plus a metalaxyl application at planting, then the Louisiana Department of Agriculture and



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Forestry notes that the registrant is willing to amend the labels to prevent a dual metalaxyl use on water seeded rice.

Ciba-Geigy Corporation, Agricultural Division, in a letter dated March 23, 1992, and signed by K.S. Stumpf, has submitted an application for an amended registration for Ridomil® 2E to add a use on water seeded rice. The petitioner submitted a revised label with directions for the new use on water seeded rice, and new magnitude of the residue crop field trial residue data supporting the proposed new use for metalaxyl application at planting of water seeded rice.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- REVISE LABELS

CONCLUSIONS

1. CBTS Conclusion on Directions for Use/Labels

- a. The label for the SLN [24(c)] registration of Ridomil 2E should be amended as the letter from Louisiana proposed. The Louisiana Department of Agriculture and Forestry needs to submit a revised label for this [24(c)] registration with the following restriction:

When using this product as directed in making a direct soil application at planting to water seeded rice, do not use Apron® treated rice seed or any other rice seed that has been treated with metalaxyl.

- b. The registrant (Ciba-Geigy Corporation) also needs to submit a revised supplemental label for EPA Reg. No. 100-607 with the following restriction:

When using this product as directed in making a direct soil application at planting to water seeded rice, do not use Apron® treated rice seed or any other rice seed that has been treated with metalaxyl.

2. CBTS Conclusion on Magnitude of the Residue - Crop Field Trials

- a. The registrant has presented an adequate amount of geographically representative crop field trial residue data to show that total metalaxyl residues in rice grain and straw are not expected to exceed the established metalaxyl tolerance of 0.1 ppm when Ridomil® is applied to water seeded rice at planting as directed.
- b. While limited, there are residue data from a metalaxyl seed treatment plus a metalaxyl pre-planting, or at planting

application that show residues are not expected to exceed the established tolerance when Ridomil® is used as directed.

- c. Since the potential exists for a dual application of metalaxyl from a seed treatment plus an at planting application and residue data from a 2X application rate show some over-tolerance residues, CBTS feels it is prudent to accept the registrant's offer to amend the proposed label to preclude this from happening. Our suggested proposed amended labeling has been described above. If the petitioner agrees to these changes and submits a revised label, then deficiency 4 on the magnitude of the residue noted in our June 12, 1992, review on SLN LA910004 is resolved.
3. CBTS Conclusion on Magnitude of the Residue - Processed Food/Feed

Since the raw agricultural commodity (rac) rice was treated at an exaggerated application rate and the metalaxyl equivalent residues in the control rice grain and bran are nearly the same as in the different treated samples of rice grain and rice bran and these levels are at or below the method's limit of quantitation (LOQ) (but not the minimum detection limit [MDL]), then there is no real concentration of residues of metalaxyl in rice bran. CBTS agrees that there is no total metalaxyl food/feed additive tolerance (FAT) required for rice processing commodities. Deficiency 5 of our review of the SLN LA-920004 dated June 12, 1992, is resolved.

RECOMMENDATION

CBTS recommends against the [24(c)] registration for use of metalaxyl on water seeded rice in Louisiana for the reason cited above in Conclusion 1a.

CBTS recommends against the proposed amended use registration for EPA Registration Number 100-607 (Ridomil® 2E Fungicide) on water seeded rice for the reason cited above in Conclusion 1b.

For further consideration of the SLN [24(c)] registration for use on water seeded rice in Louisiana the Louisiana Department of Agriculture and Forestry should be advised to submit a revised label.

For further consideration of the proposed amended use registration for EPA Registration Number 100-607 (Ridomil® 2E Fungicide) on water seeded rice the registrant should be advised to submit a revised label.

DETAILED CONSIDERATIONSDIRECTIONS FOR USELOUISIANA SLN LABEL

For this reinstated [24(c)] registration, Ridomil® 2E (EPA Reg. No. 100-607) which contains 25.1% metalaxyl active ingredient (a.i.) is applied as a broadcast soil surface spray at a rate of 1 to 2 pints Ridomil® (or 0.25 to 0.5 lb ai metalaxyl) per acre. Application is either aerial in 5 to 10 gallons of water per acre, or by ground equipment in 20 gallons of water per acre. Application is once per rice growing season prior to planting and/or establishing the flood plain. The registration for distribution and use is restricted to Louisiana.

The proposed use is to control feeder root necrosis caused by Pythium spp. in water-seeded rice grown in Louisiana. Restrictions are not to apply this product through any irrigation systems unless labeling for chemigation is followed. Plant-back or rotational restrictions for water-seeded rice are 0 days from the last Ridomil® 2E application.

After careful consideration of the data presented CBTS feels the label for the SLN [24(c)] registration of Ridomil 2E should be amended as the letter from Louisiana proposed. The Louisiana Department of Agriculture and Forestry needs to submit a revised label for this [24(c)] registration with the following restriction:

When using this product as directed in making a direct soil application at planting to water seeded rice, do not use Apron® treated rice seed or any other rice seed that has been treated with metalaxyl.

AMENDED REGISTRATION USE LABEL FROM CIBA-GEIGY

The registrant's proposed supplemental labeling or directions for use of Ridomil® containing metalaxyl a.i. on water-seeded rice are the same as in the SLN [24(c)] registration label from Louisiana, except there is no restriction on applying the product through an irrigation system. As noted above for the SLN [24(c)] registration, the registrant also needs to submit a revised supplemental label with the following restriction:

When using this product as directed in making a direct soil application at planting to water-seeded rice, do not use Apron® treated rice seed or any other rice seed that has been treated with metalaxyl.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS (MRID # 422598-05)

The registrant has submitted additional magnitude of the metalaxyl residue data on water seeded rice from an at-planting use. The title of the study is Metalaxyl - Magnitude of residues in Water-Seeded Rice Following Application of Ridomil 2E by L. W. Eudy dated March 10, 1992, and coded ABR-91018.

The residue data were generated using a modified method, AG-395, the low moisture procedure. This common moiety method that measures total metalaxyl as 2,6 dimethylaniline by GC-N/P detection has been previously reviewed (see memorandum in PP# 8F3617 by F.D. Griffith, Jr., and dated November 28, 1988). Additional method validation data for recovery of metalaxyl from rice grain and straw were generated and presented with this crop field trial residue data. Metalaxyl recoveries from rice grain spiked with metalaxyl at 0.05 ppm to 0.5 ppm ranged from 83% to 122% and from rice straw spiked at 0.05 ppm to 1 ppm ranged from 71% to 101%. Overall total metalaxyl recoveries from rice grain and straw averaged $93.9\% \pm 14.5\%$, $n = 16$. Adequate supporting chromatographic data were presented. The method has been adequately validated to gather magnitude of the residue data.

Magnitude of the residue data for rice were presented from 8 field trials from Arkansas, California, Louisiana (2), Mississippi (2), and Texas (2) on four different varieties for the crop year 1989. This represents production on 96% of the rice acreage. (see Agri-cultural Statistics, 1988). The registrant has presented adequate varietal and geographically representative data. Ridomil® 2E was applied one time direct application at-planting broadcast at a rate of 0.5 lb a.i. metalaxyl, either aerial or ground application. Four of the 8 water-seeded rice field trials had an extra plot treated with a 2X (1 lb a.i. metalaxyl) application. Total metalaxyl residues in rice straw ranged from <0.05 ppm to 0.07 ppm from the 1X application and ranged from <0.05 ppm to 0.2 ppm from the 2X application. Total metalaxyl residues in rice grain from the 1X application were <0.05 ppm, but from the 2x application total metalaxyl residues in rice grain ranged from <0.05 ppm to 0.11 ppm. No metalaxyl residues were detected in rice grain and rice straw from aerial application of Ridomil. The registrant has presented an adequate amount of crop field trial residue data to show that total metalaxyl residues in rice grain and straw are not expected to exceed the established metalaxyl tolerance of 0.1 ppm when Ridomil is applied to water seeded rice at-planting as directed.

In a separate study titled Metalaxyl: Magnitude of the Residue in Processed Food/Feed Commodities of Rice Following Treatment with Apron 25W plus Preemergence application of Ridomil 2E the registrant presented magnitude of the residue data from 2 field trials for metalaxyl from a seed treatment application plus an additional pre-emergence broadcast (non-incorporated) soil application at a rate of 2 or 6 lbs. a.i. per acre (4X or 12X). The rice grain had residues <0.05 ppm. While limited, these data support the registrant's contention that

residues of metalaxyl from a seed treatment plus pre-planting, or at-planting application are not expected to exceed the established tolerance when Ridomil is used as directed.

When the 2X application data are reviewed we note that there are over-tolerance residues on both the rice grain and straw. Since the potential exists for a dual application of metalaxyl from a seed treatment plus an at-planting application, CBTS feels it is prudent to accept the registrant's offer to amend the proposed label to preclude this from happening. Our suggested proposed amended labeling has been described above. If the registrant agrees to these changes and submits a revised label, then deficiency 4 on the magnitude of the residue noted in our June 12, 1992, review on SLN LA910004 is resolved.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

In our June 12, 1992, review of the SLN LA-92004 registration CBTS noted a deficiency with metalaxyl rice processing study data. In summary, the raw agricultural commodity rice showed no detectable total metalaxyl residues to the LOQ of <0.05 ppm; but positive total metalaxyl residues were detected in rice bran at 0.05 ppm. CBTS was unable to determine the appropriate concentration factor and thus the appropriate feed additive tolerance. CBTS reminded the registrant that we needed copies of all supporting chromatographic data for the metalaxyl rice processing study so that the Agency could estimate residues present and thus the concentration factor.

The registrant was also informed that if residues concentrate in rice bran, then a metalaxyl food/feed additive tolerance (FAT) was necessary. The appropriate FAT would be determined after review of the supporting chromatographic data from the rice processing study.

The registrant has responded and the rice processing study residue data have been reviewed by the contractor for CBRS under the direction of Branch scientists. In summary, since the rice was treated at an exaggerated application rate and the metalaxyl equivalent residues in the control rice grain and bran are nearly the same as in the different treated samples of rice grain and rice bran and these levels are at or below the method's LOQ (but not the MDL), then there is no real concentration of residues of metalaxyl in rice bran. CBTS agrees that there is no total metalaxyl FAT required for rice processing commodities. Deficiency 5 of our review of the SLN LA-920004 dated June 12, 1992, is resolved.

cc:R.F., Circ., Reviewer(FDG), 24(c)File, Amended Reg. File, Metalaxyl Reg. Std. File.

H-7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:4/30/93:fdg:edit:mjn/fdg:5/3/93.

RDI:SecHd:RSQuick:4/30/93:BrSrSci:RALoranger:5/3/93.