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

FEB 27 1987

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3387/6H5499 Metalaxyl on Fruiting Vegetables (except Curcurbits), Sugar Beets and Sugar Beet Tops. Evaluation of January 30, 1987, Amendment. (Assession Numbers 400661-1 and 400661-2) [RCB #1916]

FROM: Francis D. Griffith Jr., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Lois A. Rossi (Acting PM-21)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The review of this amendment is being expedited at the request of Edwin F. Tinsworth, Director of the Registration Division in his memorandum dated February 11, 1987, to John W. Melone, Director of the Hazard Evaluation Division.

Ciba-Geigy Corporation, Agricultural Division has submitted this amendment consisting of a cover letter, a revised Section B (new label), supplementary Section D (additional chromatographic data), a revised Section F (new tolerance proposals) and a supplementary Section G (rationale for a sugar beet molasses metalaxyl tolerance without a processing study). The amendment has been submitted in response to several deficiencies outlined in our review of metalaxyl (trade named Ridomil® and Apron®) in fruiting vegetables and sugar beets by F. D. Griffith, Jr. on September 26, 1986. The deficiencies are listed below in the order they appeared in the September 1986, review followed by the petitioner's response, then RCB comments and conclusions.

Deficiency 1a. The petitioner needs to submit a revised Section B (New Ridomil® label) which has a seven-day pre-harvest interval (PHI) for the fruiting vegetables (except cucurbits) group.

Deficiency 1b. RCB suggests the petitioner add a label caution stating that prior to mixing with any proposed tank mates, check each label to be sure the proposed uses are compatible for the fruiting vegetables (except cucurbits) group, and that there are labeled uses for the proposed tank mate(s) on the fruiting vegetables except cucurbits) group.

Petitioner's Response

The petitioner has submitted a revised label (Section B).

RCB Comments

The petitioner has added the seven day pre-harvest interval to the label for fruiting vegetables. In the General Information Section of the label the petitioner cautions producers that before tank mixing metalaxyl with other registered chemicals for any use on the label, producers should read all labels of the tank mix partners to ascertain if the partner is labeled for use on the particular crop and that use patterns are compatible with those of metalaxyl.

RCB Conclusion

Deficiencies 1a and 1b are resolved.

Deficiency 3b. RCB cannot judge the adequacy of these methods to gather metalaxyl residue data on the fruiting vegetables (except cucurbits) group without supporting chromatographic data (see Analytical Methods discussion following).

Petitioner's Response

The petitioner has submitted photocopies of 33 chromatograms showing metalaxyl standards and metalaxyl residues on tomatoes, tomato juice, and tomato pomace. The petitioner also submitted photocopies of 14 chromatograms showing metalaxyl standards, spikes, and metalaxyl residues on peppers.

RCB Comments

The petitioners presented six chromatograms of metalaxyl standards ranging from 0.04 ng to 1.0 ng metalaxyl run using the instrumentation described for method AG-395. Two chromatograms of pepper blanks showed no crop coextractives interfering where metalaxyl eluted. Recovers of matalaxyl spikes in these samples showed quantitative separation of metalaxyl from the background. Three chromatograms showed field incured residues of metalaxyl on peppers ranging from 0.13 ppm to 0.37 ppm. The chromatogram for a clean field sample showed no metalaxyl above 0.02 ppm. The petitioner has presented sufficient chromatographic supporting data for method AG-395 used in this petition. An adequate analytical method was used to generate the metalaxyl on peppers residue data.

Twelve chromatograms of metalaxyl standards ranging from 0.25ng to 8.0ng metalaxyl were run using the instrumentation described for methods AG-330 and AG-348. For the raw tomato extracts the crop blank or control samples had crop coextractives but none showed where metalaxyl eluted. A 0.05 ppm metalaxyl spike in this sample could recover 0.03 ppm metalaxyl. Four chromatograms of tomato extracts using method AG-330 had two results at 0.05 ppm-0.06 ppm metalaxyl and two residues were less than 0.05 ppm. RCB will not pursue how valid is the number for metalaxyl below 0.05 ppm. We recognize that apparent real residues at 0.01-0.03 ppm level are difficult to confirm. Using method AG-348 RCB noted a large late eluting coextractive that could interfere.

The determination of metalaxyl residues with the unidentified analytical response (UAR) requires a skilled residue analyst. Metalaxyl spikes in the control sample could be recovered at 0.03 ppm and at 0.49. Two chromatograms for treated tomatoes extracts showed metalaxyl residues of 0.14 pm and 0.62 pm. The manner in which the petitioner drew his baseline for the 0.62 ppm sample does not appear to be consisted with other sample calculations. However RCB will not pursue this point as our estimate of the answer will not materially increase the residue results. The petitioner presented a blank tomato juice chromatogram plus two chromatograms showing metalaxyl spikes at 0.03 ppm and 0.33 ppm. While numerous crop coextratives are present these UAR's do not present a problem for a skilled residue analyst.

The chromatograms of tomato juice from metalaxyl tomatoes are acceptable. The recovery samples for metalaxyl in tomato pomace show recoveries at 0.02 ppm and 0.4 ppm with potential UAR interference. RCB notes the higher the metalaxyl residue the less of a problem the UAR's becomes. The petitioner has presented sufficient chromatographic supporting data for methods AG-330 and AG-348 used in this petition. Adequate analytical methods were used to generate the metalaxyl on tomatoes residue data.

RCB Conclusion

Deficiency 3b is resolved.

Deficiency 4b. To help prevent a proliferation of tolerances RCB suggest the petitioner submit one feed additive metalaxyl tolerance for tomato pomace in a revised Section F as follows:

Petitioner's Response

The petitioner presented the following revised tolerance proposal:

We hereby request a tolerance for combined residues of the fungicide, metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester], and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy-methyl-6-methyl-phenyl)-N-(methoxyacetyl) alanine methyl ester, each expressed as metalaxyl, in or on the following raw agricultural commodities:

Fruiting Vegetables (except Cucurbits)	- 1.0 ppm
Sugar Beets	- 0.1 ppm
Sugar Beet Tops	- 0.1 ppm

PROPOSED FEED ADDITIVE TOLERANCES

We hereby request feed additive tolerances for combined residues of the fungicide, metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester], and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy-methyl-6-methylphenyl)-N-(methoxyacetyl) alanine methyl ester, each expressed as metalaxyl, in or on the following feed additive commodities:

Tomato Pomace (wet or dry) - 20.0 ppm
Sugar Beet Molasses - 1.0 ppm

RCB Comments

The petitioner has submitted the suggested tomato pomace metalaxyl tolerance. RCB will comment on the proposed sugar beet molasses metalaxyl tolerance in our discussion of the supplementary Section G (see comments following on deficiency 4F).

RCB Conclusion

Deficiency 4b is resolved. RCB notes there are no other Residue Chemistry deficiencies related to establishing a metalaxyl crop group tolerance for fruiting vegetable (except cucurbits).

Deficency 4f. The petitioner needs to conduct a processing study for sugar beets containing metalaxyl residues and present the results for the processed commodities and feed items showing the metalaxyl concentration factors. Also, the petitioner may need to propose additional food and feed additive tolerances depending on the outcome of the proposing processing study.

Petitioner's Response

The petitioner did not present results of the suggested processing study. The petitioner has provided a supplementary Section G which contains the rationale for the proposed sugar beet molasses metalaxyl tolerance, a letter from Gustafson, Inc., requesting a waiver for the suggested sugar beet processing study, and letter with supporting documentation from the Beet Sugar Development Foundation detailing how a 7X concentration factor from sugar beet to sugar beet molasses is appropriate.

RCB Comments

RCB reiterates its previous conclusion that while metalaxyl residues on sugar beets and sugar beet tops are not expected to exceed the proposed 0.1 ppm tolerance under the conditions of the proposed use, the petitioner needs to conduct a sugar beet processing study using field incurred metalaxyl residues and process those beets into molasses, sugar, and dehydrated pulp. Metalaxyl residues data are needed for each of these commodities, and if metalaxyl residue concentration is shown on any of these commodities, then the petitioner should propose the appropriate food or feed additive tolerances.

In the cover letter the petitioner states a sugar beet processing study is near completion. RCB should be able to review the results of the metalaxyl sugar beet processing study from a soil treatment use in February, 1987. We defer judgement on the adequacy of this study to address our concerns until we have actually reviewed the entire study results.

In the revised Section G the petitioner proposes a 7X concentration factor (theoretical) based on data from the Beet Sugar Development Corporation. No mention is made of sugar or dehydrated pulp. The petitioner will have to consider the question food/feed additive tolerances for metalaxyl in sugar, pulp, and molasses further, during the sugar beet processing study.

A letter from the Beet Sugar Development Foundation in Fort Collins, Colorado, dated December 19, 1986, signed by Stephen Reynolds provides information on molasses production from sugar beets. RCB notes that molasses production from sugar beets was 4% to 6% in straight houses and 5% to 7% in Steffen houses. If all of the sugar beets had 0.1 ppm metalaxyl and all of this metalaxyl went into molasses then RCB estimates a 20X concentration factor. Presumeably the appropriate concentration factors will be determined in the requested sugar beet processing study.

Gustafson, Inc. of Dallas, Texas, in a letter dated December 12, 1986, and signed by J. C. Rockwell requests EPA reconsider the imposition of the requirement of a processing study for sugar beets. Three arguments were presented to back up the the waiver request. The first argument centers on a use rate of metalaxyl per acre for seed treatment. RCB points out this is not a soil application use but a seed treatment use and essentially all of the ^{14}C-residue on the seed appeared in the beet. The second argument centers on this is a minor use pattern. Sugar beets are not a minor crop. Considering the acreage involved and the amount of seed treated, this is minor use on a major crop. The third argument centers on potential crop loss. This is not an argument in RCB preview; thus no comments will be made.

RCB Conclusions

Deficiency 4f is not resolved. RCB reiterates its conclusion of the September 26, 1986, review. The petitioner needs to complete a sugar beet processing study using field incurred metalaxyl residues at the proposed tolerance and process these beets into sugar, molasses and dehydrated pulp. Residues data are needed for each of the commodities. If metalaxyl concentrates in any of these commodities appropriate food and/or feed additive tolerances should be proposed. Deficiency 4f is the only unresolved deficiency remaining in this petition.

RCB Recommendation

RCB can recommend for the prorposed metalaxyl tolerance of 1 ppm on the crop group fruiting vegetables (except Curcurbits) being established. RCB can also recommend that the proposed metalaxyl tolerance of 20 ppm on tomato pomace (wet or dry) be established. Both of these tolerances need TOX Branch and Exposure Assessment Branch concurrance before being established.

RCB can not recomend for the requested metalaxyl tolerance in sugar beets and sugar beet tops at this time for the reason cited in our conclusion 4f above.

For further consideration of the metalaxyl in sugar beets and sugar beet tops tolerances the petitioner should complete and submit the sugar beet processing study now in progress, report the results to RCB, and propose the appropriate food or feed additive tolerance as necessary. The beet processing study should include analyses for sugar, dehydrated beet pulp, and for beet molasses.

The product Manager should note that Section G in this submission states that the results of the sugar beet processing study will be submitted to the Agency in February, 1987. The Product Manager should be on the look out for this action when it arrives in RD.

RCB:TS-769C:Reviewer(FDG):CM#2:Rm814B:557-0826:vg:2/25/87:edited:fdg:2/26
cc: RF, PP#6F3387,SF,PM-21,PMSD/ISB, Reviewer, TOX, EAB, EEB, FDA, Circu.
RDI:Section Head:R.S.Quick:2/19/87:R.D.Schmitt:2/20/87