R.E.

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

OCT 18 1989

Memorandum:

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP#7F3553/FAP#7H5541. Thiabendazole in/on Stored Corn Grain. Amendment dated June 9, 1989 (MRID#'s 411257-01 and -02, DEB#'s 5449 and 5450).

FROM: Jerry B. Stokes, Chemist
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Philip V. Errico, Head, Section III
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Susan Lewis, PM-21
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch
Health Effects Division (H7509C)

The petitioner, Merck Sharp & Dohme Research Laboratories has submitted an amendment in response to deficiences cited in the DEB review of PP#7F3553/FAP#7H5541 (See memo of July 29, 1988, J. Stokes) for the proposed use of fungicide thiabendazole (TBZ) in/on corn (freshly harvested and slowly dried and stored). The amended data consist of a revised Section B, a grain dust study, a wet milling study, a revised section F, and additional data for Section A. The petitioner also submitted revised Sections E and G.

Each deficiency cited in the 7/29/88 review of PP#7F3553/FAP#7H5541 (memo of J. Stokes) is restated using the numbering of the original review.

Summary of DEB Comments/Conclusions:

1. Deficiencies 3, 4, 6a, 6b, 6c, 7, 9a, 9c, and 10 cited in PP#7F3553/FAP#7H5541 are resolved.

2. Petitioner needs to submit additional data for grain dust for the proposed use. Deficiency 5 (PP#7F3553/FAP#7H5541) remains outstanding.

Detailed Considerations:

Deficiency 3, memo of 7/29/88:

"The proposed tolerance of 20 ppm for residues of TBZ may not be adequate to cover estimated residues from this post-harvest use on freshly harvested corn grain. Treatment and sampling procedures may lead to over tolerance residues for properly dosed corn grain. The tolerance request should be raised to 25 ppm for corn, grain (post-H). A revised Section F should be submitted."

Petitioner's Response, 6/9/89:

A revised Section F has been submitted for the establishment of a 25 ppm tolerance for the residues of TBZ and it metabolite, 5-OH-TBZ, for the proposed post-harvest use on freshly harvested corn grain.

DEB Comments/Conclusions:

This deficiency is now resolved.

Deficiency 4, memo of 7/29/88:

"The label must state the maximum/minimum spray volume, clarify what a "sufficient carrier" is, and place a label restriction that the pesticide can only be applied to freshly harvested corn grain which is destined for low temperature drying and storage. A revised Section B should be submitted."

Petitioner's Response, 6/9/89:

A revised Section B has been submitted with the recommended label restriction, and with the application rate and carrier clearly defined.

DEB Comments/Conclusions:

This deficiency is now resolved.

Deficiency 5, memo of 7/29/88:

"The petitioner needs to submit residue data for corn grain dust which reflects the proposed use."

Petitioner's Response, 6/9/89:

The petitioner has submitted the following study, "Thiabendazole Processing Trial/Corn Dust Study, MRID#411257-01, and a revised Section F with the feed additive tolerance of 400 ppm for corn screenings.

In the study, treated and check corn grain samples were cleaned by screening (2449 um screen) to remove the chaff, broken pieces,

and foreign material. According to the submitted procedure, samples were removed from the screened grain and air washed to remove any grain dust in a specially designed tumbling apparatus. Corn dust (independently obtained from an alternative source) was screened through a series of sieves (1000, 500, 250, 212, and 106 um). The grain dust fraction <106 um in particle size was added to a 20 lb load of freshly cleaned grain sample in 3 parts over a 30-minute period until the dust had been added to represent approximately 0.2% by weight (ca. 18g). For the check sample at the end of this 30 minutes, the grain was air washed by the vacuum/trapping system to reclaim the added dust. For a representative treated sample, after the dust had been applied, the grain was dosed with MERTECT-340F according to the proposed use (0.03 fl. oz./bu will give ca. 20 ppm TBZ residues) and the treated sample tumbled intermittently during an overnight drying period. After the drying time the grain was air washed/vacuumed, and the aspirated dust was trapped in a preweighed fibre-glass filter. The filter was weighed again to determine the amount of dust captured. The treated samples were measured for TBZ residues by the PAM II analytical enforcement methodology. Levels of TBZ in grain dust ranged from 2397 to 2652 ppm (ca. 125X concentration) with recoveries from 55 to 86%.

DEB Comments/Conclusions:

The grain dust used in this study was of very small particle size <106 um. According to literature references, the average grain dust has approximately 50% of the particles below this size. Therefore, all the chaff and larger aspirated particles were excluded from the MERTECT-340F application. This is a severe worst case and may not be representative of common commercial practices. When grain dust is used in feed mixes, the dust may or may not be screened to remove foreign material and other elevator trash, but is not commonly sieved through such small opening before use in feeds. Thus the measured TBZ residues (ca. 2500 ppm) on the <106 um particles are probably much too high to represent typical commercial grain dust.

The petitioner has stated that grain dust is of little nutritive value and will not be incorporated into animal feeds to any extent. However, according to representatives of the grain industry, feed mills, livestock researchers, and various operators of plants producing feed mixes of pelleted grain dust, grain dust has nutritive value and is presently used in animal feeds and mixes at an average of 18% level for beef and diary cattle, swine, and poultry. Also grain dust is normally a mixture of dusts, i.e., corn, wheat, soybeans, sorghum, milo, barley and/or oats. The US annually produces <500,000 tons of grain dust of which corn, as a major contributor, represents approximately 40% of this total. Since the commercial dust is a mixture of grains DEB has recommended (See memo of conference, 8/21/89, P. Errico, malathion/grain dust discussion, DEB files) that a tolerance be established for "grain dust" and not a tolerance for each grain variety, e.g., "corn dust".

Based upon the data from the wet milling process reviewed in this memo, the corn screenings gave TBZ residues <300 ppm. The petitioner has proposed that a 400 ppm tolerance be established for corn screenings and has submitted a Section F. The petitioner stated that this fraction contained a large fraction of dust and fine hull/bran fragments. The residue adequately support this request and a tolerance could be established for 400 ppm for TBZ residues in corn screenings for the proposed use.

However, this will not be a substitute for the requirement of the establishment of a separate TBZ tolerance on grain dust. Based upon the treatment of only the small particle size (<106 um), DEB cannot determine an adequate tolerance for TBZ residues in grain dust for the proposed use. Additional data are needed using dust more comparable to the common commercially available grain dust before any sieving or screeening procedures are applied which are not normally performed on grain dust. Although, commercial dust is a mixture, for the purposes of collecting data for the proposed use on corn, the petitioner should use "corn dust" for the small scale dust experiments. DEB agrees that the submitted grain dust study protocol (See MRID#411257-01) appears adequate to provide sufficient residue data in regards to the proposed use on corn.

This deficiency is still outstanding.

Deficiencies 6a, 6b, & 6c, memo of 7/29/88:

"Residue data are needed for the wet milling process for corn grain. The need for any additions and/or changes in the proposed feed and/or food additive tolerances, and subsequently in the established tolerances for meat, fat, meat byproducts, milk, and eggs, will be assessed after the wet milling processing data has been submitted and reviewed." (6a)

"Depending on the results of the wet milling processing study, and based on the residue data, if and when a thiabendazole tolerance is established for corn, grain (post-H), then feed additive tolerances should be established at these tentative levels as follows:

corn, milled fractions (exc bran and soapstock) (post-H)	40 ppm
corn bran (post-H)	145 ppm

A revised Section F should be submitted." (6b)

"Depending on the results of the wet milling processing study, and based on this data, if and when a thiabendazole tolerance is established for corn, grain (post-H), then food additive tolerances should be established at these tentative levels as follows:

corn, milled fractions (exc bran) (post-H) 40 ppm
corn bran (post-H) 145 ppm

A revised Section F should be submitted." (6c)

Petitioner's Response, 9/89:

The petitioner has submitted the following study, "Thiabendazole Processing Trial/Corn Wet Mill Study, MRID#411257-02, and a revised Section F with the feed and food tolerances and stated above. One sample of treated corn grain was processed; two samples per processed commodity were analyzed in duplicate.

In the processing study, treated (120 lb) and check (136 lb) corn grain samples were cleaned by screening and aspiration to remove the dust, chaff, broken pieces, and foreign material. The cleaned corn grain was steeped in a sulfurous acid solution maintained between 120 and 125°F for a minimum of 40 hours. The steepwater was removed and the steeped corn was milled and separated into endosperm, germ, and fiber. These fraction were further processed into starch, gluten, crude oil, presscake, refined oil, and soapstock. All samples, both for treated and check grain, were analyzed for TBZ residues by the PAM II enforcement methodology.

The following TBZ residues were measured in the various processed commodities and in the starting grain.

Commodity	Residue, ppm of thiabendazole			
	Treated grain	Check grain	Spiked grain samples	
			ppm added	% Recovery
corn grain, whole	14.4 - 15.9	---	---	---
corn grain, screened	9.2 - 10.7	0.02	---	---
corn screenings	289 - 340	1.6	5;25;100;300	99;94;100;97
germ	8.5 - 8.7	0.10 - 0.14	---	---
hull/bran	7.3 - 7.7	0.03	---	---
gluten	7.3 - 7.4	0.03	0.1;0.4;1;2	96;105;97;99
starch	0.7	0.00	0.04;0.2;0.1;1	97;102;101;97
steepwater concentrate	3.2 - 3.4	---	0.1;0.4;2;4	104;105;99;94
presscake, expelled	8.5 - 9.1	0.18 - 0.20	0.6;2;6;10	98;94;95;90
oil, crude	6.2 - 6.9	---	---	---
oil, refined	5.3 - 5.7	0.12	---	---
soapstock	10.3 - 12.2	0.16 - 0.21	---	---

DEB Comments/Conclusions:

Based upon the measured TBZ residues in the uncleaned treated corn grain, approximately 38% of the TBZ residues were removed on the initial screening and aspiration. Only 68% of the beginning TBZ residue remained on the cleaned treated corn grain. A tally of the residues measured in the processed fractions showed a 50% lost of the measured 68% on the cleaned grain. However, all the fractions, except the initial screened and aspirated waste, gave residues below the requested 25 ppm tolerance. Therefore a 25 ppm tolerance would adequately cover any expect residues for the fractions from the wet milling process, except the initial screening waste. The dry mill process showed concentration in the milled corn fraction (exc bran and soapstock) and corn bran. The requested 40 ppm and 145 ppm tolerances would adequately cover any TBZ residues from the proposed use.

Based upon the data from this wet milling process, the corn screenings from the initial cleanup gave TBZ residues up to 340 ppm (21X). The petitioner has proposed that a 400 ppm tolerance be established for corn screenings. The residue adequately support this request and a tolerance could be established for 400 ppm for TBZ residues in corn screenings for the proposed use.

Deficiency 7, memo of 7/29/88:

"After reviewing the data submitted in this petition, revocation of the established tolerances of 10 ppm for the r.a.c., grapes, and 150 ppm for grape pomace (wet or dry) are not necessary to satisfy any Residue Chemistry Branch concerns. A revised Section F which deletes this revocation request should be submitted if there are no other Agency data requirements and if it is the desire of the petitioner to retain the established tolerances."

Petitioner's Response, 6/9/89:

A revised Section F has been submitted to retain the established tolerances for the TBZ residues for r.a.c. grapes (10 ppm) and for grape pomace (150 ppm).

DEB Comments/Conclusions:

This deficiency is now resolved.

Deficiency 9a, memo of 7/29/88:

"The established tolerances of 0.1 ppm for eggs, poultry meat, meat byproducts (exc kidney) and fat are adequate to cover estimated secondary residues of TBZ and its metabolite, 5-OH-TBZ, from the proposed use. A tolerance should be established for poultry kidney at 0.2 ppm, and poultry meat byproducts should be changed as follows:

poultry meat byproducts (exc kidney) 0.1 ppm

A revised Section F should be submitted."

Petitioner's Response, 6/9/89:

A revised Section F has been submitted for the establishment of a 0.2 ppm tolerance for poultry kidney, and a 0.1 ppm tolerance for poultry meat byproducts (exc kidney) for the TBZ residues for the proposed post-harvest use on freshly harvested corn grain.

DEB Comments/Conclusions:

This deficiency is now resolved.

Deficiency 9c, memo of 7/29/88:

" For the proposed use the established tolerances of 0.1 ppm for secondary residues of TBZ and its metabolite, 5-OH-TBZ, in cattle, goat, hogs, horses, and sheep meat byproducts should be changed as follows:

meat byproducts (exc. liver, kidney)	0.1 ppm
liver	0.4 ppm
kidney	0.4 ppm

Fat and meat tolerances remain at 0.1 ppm. A revised Section F should be submitted."

Petitioner's Response, 6/9/89:

A revised Section F has been submitted for the establishment of a 0.4 ppm tolerances for liver and kidney, and a 0.1 ppm tolerance for meat byproducts (exc liver, kidney) for the TBZ (and 5-OH-TBZ) residues for the proposed post-harvest use on freshly harvested corn grain.

DEB Comments/Conclusions:

This deficiency is now resolved.

Deficiency 10, memo of 7/29/88:

"The petitioner should request clearance for one inert in the MERTECT-340F formulation." (See Confidential Appendix, memo of 7/29/88, J. Stokes)

Petitioner's Response, 6/9/89:

The inert is cleared under 40 CFR 180.1001(c) under its common name. Technical Data Bulletins for this inert, and for another inert which is used in the MERTECT-340F formulation are submitted.

DEB Comments/Conclusions:

This deficiency is now resolved.

Recommendations:

DEB cannot recommend the establishment of the proposed thiabendazole tolerances until deficiency 5 is adequately addressed.

cc: J. Stokes (DEB); PP#7F3553/FAP#7H5541; Thiabendazole S.F.; E. Eldredge (PMSD/ISB); R.F.; Circulation (7); R. Schmitt (DEB)
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