

11/18/93

THIABENDAZOLE (CASE 2670/CODE 60101) UNOFFICIAL RESIDUE CHEMISTRY DATA SUMMARY THROUGH 11/18/93 ¹ REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH CODEX ²		
Guideline Number and Topic ³	Are Data Requirements Satisfied?	MRID(s) ⁴
171-3 Directions for use		
171-4(a) Plant Metabolism	Y ⁶	41872901, 41872902 41872903
171-4(b) Animal Metabolism	Y ⁸	42057901, 42011701
171-4(c) Residue Analytical Methods - Plants	N ⁷	
171-4(d) Residue Analytical Methods - Animals	N	
171-4(e) Storage Stability	N ⁸	42515801, 42515802, 42568001, 42660302
171-4(k) Crop Field Trials ⁹		
171-4(k) Root and Tuber Vegetables Group		
Carrots	Y	
Potatoes [see 171-4(l)]	N ¹⁰	42660302
Sugar beets [see 171-4(l)]	N	
Sweet potato	N ¹¹	42660301
171-4(k) Leaves of Root and Tuber Vegetables		
Sugar beet tops	N	
171-4(k) Legume Vegetables (succulent/dried)		
Beans (dried)	N	
Peas (field)	N	
Soybeans [see 171-4(l)]	N	
171-4(k) Foliage of Legume Vegetables		
Bean vines and hay	N	
Pea vines and straw	N	
Soybean forage and hay	N	
171-4(k) Cucurbit Vegetables Group		
Melons/cantaloupes	N	
Squash (hubbard)	N	
171-4(k) Citrus Fruits Group [see 171-4(l)]	N ¹²	42568001
Grapefruit	N	
Lemons	N	
Oranges	N	
171-4(k) Pome Fruits Group	N ¹³	42515802
Apples [see 171-4(l)]	N	
Pears	N	
171-4(k) Small Fruits and Berries Group		
Grapes [see 171-4(l)]	N	
Strawberries	N	
171-4(k) Cereal Grains Group		

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UNOFFICIAL RESIDUE CHEMISTRY DATA SUMMARY THROUGH 11/18/93¹
REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH
CODEX²

Guideline Number and Topic ³	Are Data Requirements Satisfied?	MRID(s) ⁴
Rice [see 171-4(l)]	N	
Wheat [see 171-4(l)]	N ¹⁴	42718401
171-4(k) Forage, Fodder, and Straw of Cereal Grains		
Rice straw	N	
Wheat forage and straw	N ¹⁵	42718401
171-4(k) Miscellaneous Commodities		
Avocados	N	
Bananas	N	
Mangoes	N	
Mushrooms	N ¹⁶	425989-01
Papayas	Y	
171-4(l) Processed Food/Feed		
Apples	N ¹⁷	42515802
Beans (dried)	N	
Citrus	N ¹⁸	42568001
Grapes	N	
Potato	N ¹⁹	42660302
Rice	N	
Soybeans	N	
Sugar beets	N	
Wheat	N ²⁰	42718401
171-4(j) Meat/Milk/Poultry/Eggs	N	
171-4(f) Potable Water	R ²¹	
171-4(g) Fish	R ²²	
171-4(h) Irrigated Crops	R ²³	
171-4(i) Food Handling Establishments	N/A	
171-5 Reduction of Residues	N/A	
171-11 Tobacco Use	N	

¹Phase 4 review issued 2/20/91. CBRS 8922, 12/9/91, R.B. Perfetti: Some Phase 4 requirements are amended, provided specified crops are removed from all labels. This summary is unofficial and subject to correction.

²Codex regulates TBZ in plants, and TBZ plus 5-OH-TBZ in animals.

³N/A = Guideline requirement not applicable.

⁴MRIDs that were reviewed in the current submission are designated in shaded type.

⁵CBRS 8192, 3/11/92, L. Cheng: Metabolism studies on wheat, soybean, and sugar beet were reviewed. The nature of TBZ in plants is understood. CBRS recommended that TBZ plus BNZ and its conjugates be regulated in plants.

⁶Memo, 2/14/92, L. Cheng: The Metabolism Committee recommended that TBZ, 5-OH-TBZ plus BNZ and its conjugates be regulated in animal commodities.

⁷CBRS 10954, 4/15/93, R.B. Perfetti: Data collection and tolerance enforcement methodology capable of quantifying free and conjugated BNZ must be developed. Methods proposed for enforcement must undergo independent laboratory validation prior to being submitted for EPA lab validation.

⁸CBRS 10954, 4/15/93, R.B. Perfetti. MRIDs 4251801, 4251802: The submitted storage stability data indicate that thiabendazole per se is stable in apples, apple juice, and dried pomace for at least 273 days (9 months) at -15 °C. The required residue and processing studies must be accompanied by supporting storage stability data for thiabendazole and BNZ.

CBRS 11216, 7/30/93, J. Abbotts. MRID 42568001: The submitted storage stability data indicate that residues of parent thiabendazole are stable during storage at -26°C for at least 9 months in citrus fruit, oil, molasses, and peel/pulp. Data are required for residues of the metabolite BNZ.

CBRS 11601, 8/3/93, J. Abbotts. MRID 42660302: Residues of thiabendazole and BNZ in whole potatoes and wet peel are stable for 3 months during frozen storage. Data are required for frozen storage of nearly two years to support residue data in potato and potato processed commodities.

The submitted storage stability data indicate that thiabendazole and benzimidazole are stable in mushrooms stored at -23 °C for a least 189 days (6 months). However, samples from the submitted residue study were stored frozen for up to 18 months prior to analysis. The registrant has indicated that the ongoing storage stability study will be continued up to 18 months. Conclusions regarding the adequacy of storage stability data for mushrooms are reserved pending review of the 18-month storage interval data. (D. Miller, 11/18/93, CBRS No. 11161)

⁹Merck intended to delete use on sugar beets, grapes, peas, avocados, dried beans, mangoes, soybeans, and rice.

¹⁰CBRS 11601, 8/3/93, J. Abbotts. MRID 42660302: Judgment is reserved on residue data on BNZ and conjugates, pending a validated method. Supporting storage stability data are required. Residues of parent thiabendazole concentrate during potato processing in dry peel.

¹¹CBRS 11601, 8/3/93, J. Abbotts. MRID 42660302: Judgment is reserved on residue data on BNZ and conjugates, pending a validated method. Supporting storage stability data are required. Even with the deficiencies identified, the data indicate that treatment at registered rates may lead to residues which exceed the existing tolerance for sweet potato of parent thiabendazole.

¹²CBRS 10168, 7/27/92, C.L. Olinger. MRID 42315701: This preliminary report under FIFRA 6(a)(2) guidelines indicates that treatment at registered rates may result in residues in excess of the existing tolerance for citrus fruit.

CBRS 11216, 7/30/93, J. Abbotts. MRID 42568001: Additional data are required before the residue study and the processing study can be considered acceptable. Even with the deficiencies identified, available data indicate that treatment at registered rates may result in residues in excess of the existing tolerance for citrus fruit.

¹³CBRS 10954, 4/15/93, R.B. Perfetti: The residue studies on apples and pears and the apple processing study are not adequate. CBRS has concluded that BNZ and conjugates are to be included in the tolerance expression. After adequate analytical methodology is developed that is capable of detecting BNZ and conjugates, residue data for BNZ must be submitted reflecting registered uses on apples and pears.

¹⁴CBRS 11792, 7/28/93, L. Cheng: Residue data on wheat crop and processed commodities were adequate for early season use only, pending resolution of analytical methodology.

¹⁵CBRS 11792, 7/28/93, L. Cheng: Residue data on wheat crop and processed commodities were adequate for early season use only, pending resolution of analytical methodology.

¹⁶ Despite the fact that only the parent thiabendazole and free BNZ were determined, the residue study on mushrooms is considered adequate. CBRS has sufficient information to conclude that it is only the parent thiabendazole and (possibly) free BNZ residues which are the residues of potential concern in mushrooms, and will not require either the development of a method to detect BNZ conjugates in mushrooms or the submission of additional data regarding BNZ conjugates in mushrooms.

The registrant must amend the label limiting the maximum single direct spray application to 0.12 lb ai/1000 ft² or propose an increase in the tolerance for thiabendazole residues in on mushrooms (TOX considerations permitting).

The submitted storage stability data indicate that thiabendazole and benzimidazole are stable in mushrooms stored at -23 °C for a least 189 days (6 months). Samples from the submitted residue study were stored frozen for up to 18 months prior to analysis. The registrant has indicated that the ongoing storage stability study will be continued up to 18 months. Conclusions regarding the adequacy of storage stability data for mushrooms are reserved pending review of the 18-month storage interval data. (D. Miller, 11/18/93, CBRS No. 11161)

¹⁷CBRS 10954, 4/15/93, R.B. Perfetti: Data from the apple processing study indicate that thiabendazole residues concentrate approximately 12x in dry apple pomace. However, data are needed to determine the potential for concentration of BNZ. The appropriate level for a feed additive tolerance will be determined after (i) the newly defined apple tolerance level is determined, and (ii) data are available to determine the potential for concentration of combined thiabendazole and BNZ residues.

¹⁸CBRS 11216, 7/30/93, J. Abbotts. MRID 42568001: Additional data are required before the residue study and the processing study can be considered acceptable. Even with the deficiencies identified, available data indicate that treatment at registered rates may result in residues in excess of the existing tolerance for citrus fruit.

¹⁹CBRS 11601, 8/3/93, J. Abbotts. MRID 42660302: Judgment is reserved on residue data on BNZ and conjugates, pending a validated method. Supporting storage stability data are required. Residues of parent thiabendazole concentrate during potato processing in dry peel.

²⁰CBRS 11792, 7/28/93, L. Cheng: Residue data on wheat crop and processed commodities were adequate for early season use only, pending resolution of analytical methodology.

²¹Pending submission of the rice label prohibiting the diversion of water from treated fields to drinking water supplies.

²²Pending submission of the rice label prohibiting the diversion of water from treated fields to drinking water supplies.

²³Pending submission of the rice label prohibiting the diversion of water from treated fields to drinking water supplies.

cc: D. Miller; Thiabendazole List B File; J. Ellenberger (SRRD).

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