

US EPA ARCHIVE DOCUMENT

11/18/93

**THIABENDAZOLE (CASE 2670/CODE 60101)**  
**UNOFFICIAL RESIDUE CHEMISTRY DATA SUMMARY THROUGH 11/18/93<sup>1</sup>**  
**REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH**  
**CODEX<sup>2</sup>**

Guideline Number and Topic <sup>3</sup>	Are Data Requirements Satisfied?	MRID(s) <sup>4</sup>
171-3 Directions for use		
171-4(a) Plant Metabolism	Y <sup>6</sup>	41872901,41872902 41872903
171-4(b) Animal Metabolism	Y <sup>8</sup>	42057901,42011701
171-4(c) Residue Analytical Methods - Plants	N <sup>7</sup>	
171-4(d) Residue Analytical Methods - Animals	N	
171-4(e) Storage Stability	N <sup>8</sup>	42515801,42515802, 42568001,42660302
<b>171-4(k) Crop Field Trials<sup>8</sup></b>		
<b>171-4(k) Root and Tuber Vegetables Group</b>		
Carrots	Y	
Potatoes [see 171-4(l)]	N <sup>10</sup>	42660302
Sugar beets [see 171-4(l)]	N	
Sweet potato	N <sup>11</sup>	42660301
<b>171-4(k) Leaves of Root and Tuber Vegetables</b>		
Sugar beet tops	N	
<b>171-4(k) Legume Vegetables (succulent/dried)</b>		
Beans (dried)	N	
Peas (field)	N	
Soybeans [see 171-4(l)]	N	
<b>171-4(k) Foliage of Legume Vegetables</b>		
Bean vines and hay	N	
Pea vines and straw	N	
Soybean forage and hay	N	
<b>171-4(k) Cucurbit Vegetables Group</b>		
Melons/cantaloupes	N	
Squash (hubbard)	N	
<b>171-4(k) Citrus Fruits Group [see 171-4(l)]</b>		
Grapefruit	N <sup>12</sup>	42568001
Lemons	N	
Oranges	N	
<b>171-4(k) Pome Fruits Group</b>		
Apples [see 171-4(l)]	N <sup>13</sup>	42515802
Pears	N	
<b>171-4(k) Small Fruits and Berries Group</b>		
Grapes [see 171-4(l)]	N	
Strawberries	N	
<b>171-4(k) Cereal Grains Group</b>		

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

<sup>1</sup>Phase 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.

<sup>2</sup>Codex regulates TBZ in plants, and TBZ plus 5-OH-TBZ in animals.

<sup>3</sup>N/A = Guideline requirement not applicable.

<sup>4</sup>MRIDs that were reviewed in the current submission are designated in shaded type.

<sup>5</sup>CBRS 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.

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

<sup>7</sup>CBRS 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.

<sup>8</sup>CBRS 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)

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

<sup>10</sup>CBRS 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.

<sup>11</sup>CBRS 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.

<sup>12</sup>CBRS 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.

<sup>13</sup>CBRS 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.

<sup>14</sup>CBRS 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.

<sup>15</sup>CBRS 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.

<sup>16</sup> 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 ft<sup>2</sup> 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)

<sup>17</sup>CBRS 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.

<sup>18</sup>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.

<sup>19</sup>CBRS 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.

<sup>20</sup>CBRS 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.

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

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

<sup>23</sup>Pending 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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