

US EPA ARCHIVE DOCUMENT

3-9-94

MEMORANDUM

SUBJECT: PP #4F04320. Triadimenol for Use as a Seed Treatment in or on **Wheat, Barley and Oats**. Proposed Increase in Tolerances for Straw. Evaluation of Analytical Method and Magnitude of the Residue Data.

MRID Nos.: None
CBTS No: 13268
DP Barcode: D199645

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Miles, Inc. requests an amendment to 40CFR §180.450 to increase tolerances for the combined residues of the fungicide triadimenol (KWG-0519, β -(4-chlorophenoxy)- α -(1,1-dimethylethyl)-1H-1,2,4-triazol-1-ethanol) and its butanediol metabolite (KWG-1342, 4-(4-chlorophenoxy)-2,2-dimethyl-4-(1H-1,2,4-triazol-1-yl)-1,3-butanediol) calculated as triadimenol in/on wheat straw, barley straw and oats straw from 0.1 ppm to 0.2 ppm.

CONCLUSIONS

1. CBTS concludes that the geographic representation of the available wheat, barley and oats straw residue data is adequate to support the requested tolerance increase.

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2. The cited wheat, barley and oats straw residue data support an increase in the established tolerance for residues of triadimenol and its butanediol metabolite in/on wheat straw, barley straw and oats straw from 0.1 ppm to 0.2 ppm.
3. CBTS concludes that considerations of proposed use pattern, impurities in the technical product, analytical methods, metabolism and storage stability have been addressed in our 11/4/93 memorandum. We continue to find that there are no outstanding deficiencies with respect to these issues which would preclude an increase in the wheat, barley and oats straw tolerance as requested in this petition.
4. Due to the difference in the tolerance expression, as well as the tolerance levels, compatibility between U.S. and Codex tolerances is not possible at this time.

RECOMMENDATIONS

TOX considerations permitting, CBTS recommends in favor of increasing the existing tolerance (40CFR §180.450(a)) for the combined residues of triadimenol and its butanediol metabolite (calculated as the parent) in/on wheat straw, barley straw and oats straw to 0.2 ppm.

Detailed Considerations

Background

The petitioner, Miles, Inc. previously submitted crop field trial data to support the registration of a new triadimenol flowable formulation, BAYTAN 2.6 FS, for use as a seed treatment on wheat, barley and oats. In our review dated 11/4/93 (D. Davis), CBTS was unable to recommend in favor of the requested registration based on our conclusion that the existing triadimenol tolerances for wheat straw, barley straw and oats straw are not adequate to cover residues of triadimenol and its butanediol metabolite likely as a result of the seed treatment use proposed. Prior to Section 3 registration of BAYTAN 2.6 FS for use as a seed treatment, the registrant was advised that CBTS would require either substantial evidence to invalidate the over-tolerance residue reported for wheat straw, or would require amendment of 40CFR §180.450 to increase the tolerances for wheat straw, barley straw and oats straw to 0.2 ppm. In response to our recommendation, Miles, Inc. has petitioned to increase the subject tolerances for wheat straw, barley straw and oats straw to 0.2 ppm.

11/4/93 CBTS Memorandum Summary

The conclusions and recommendations from our 11/4/93 memorandum are listed below.

CONCLUSIONS

1. *The manufacture of technical triadimenol has been adequately discussed in previous reviews. Impurities in the*

technical product are not likely to cause a residue problem. Clearance of the inerts in this formulation is under the purview of RD.

2. *CBTS concludes that the proposed use directions submitted for BAYTAN 2.6 FS for use on wheat, barley and oats as a seed treatment are adequate and reflect the application pattern used to generate residue data presented in support of this registration request.*
- 3a. *Adequate analytical methodologies are available in PAM II for the enforcement of the existing/suggested tolerances in/on wheat, barley and oats.*
- 3b. *Miles Method 80488, with modifications as described in this submission, has been adequately validated for the collection of residue levels of triadimenol and its butanediol metabolite, KWG-1342 in/on wheat, barley and oat grain, forage and straw.*
- 4a. *The geographic representation of the available wheat, barley and oat residue data is adequate to support registration of Baytan 2.6 FS for use as a seed treatment in/on wheat, barley and oats.*
- 4b. *CBTS concludes that existing tolerances established under 40CFR §180.450 for residues resulting from the application of the active ingredient, triadimenol, to wheat, barley and oats are adequate to cover residues in/on wheat forage and grain, barley forage and grain and oat forage and grain likely as a result of the proposed use in this submission.*
- 4c. *The existing triadimenol tolerances for wheat straw, barley straw and oats straw are not adequate to cover residues of triadimenol and its butanediol metabolite likely as a result of the use proposed in this submission. Prior to Section 3 registration of this formulation for use as a seed treatment, CBTS will require either substantial evidence to invalidate the over-tolerance residue reported for wheat straw, or will require amendment of 40CFR §180.450 to increase the tolerances for wheat straw, barley straw and oats straw to 0.2 ppm.*
- 4d. *CBTS concludes that residues of triadimenol and its butanediol metabolite in processed grain commodities are not likely to exceed the established RAC tolerances for wheat, barley and oats. No food additive tolerances are required to support registration of this formulation.*
5. *CBTS concludes that existing tolerances are adequate to cover secondary residues of triadimenol likely to occur in animal commodities as a result of the seed treatment use proposed in this registration request.*
6. *The frozen stability of residues of triadimenol and its butanediol metabolite in wheat, barley and oat RACs have been adequately demonstrated for the time period under which field trial samples were stored.*

RECOMMENDATIONS

CBTS cannot, at this time, recommend in favor of registration of Baytan 2.6 FS for use as a seed treatment on wheat, barley and oats for the reason cited in Conclusions 4c, above.

Prior to registration of this formulation, CBTS will require resolution of the issues surrounding straw over-tolerance residue levels.

Residue Data

Wheat straw, barley straw and oats straw data cited to support the proposed tolerance increases are summarized below.

Table 1. Wheat Straw Residue Data - MRID No. 427121-01¹

Matrix	Location/Field Trial ID	Variety	PHI (days) ²	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ³
Straw	MN/251-BT001-89H	Spring	83	0.11	0.04	0.15
	ND/251-BT002-89H	Spring	90	<0.01	<0.01	0.02
	ID/452-BT004-89H	Spring	127	0.01	<0.01	0.02
	WA/454-BT006-89H	Spring	108	<0.01	<0.01	0.02
	IN/HIN-BT008-89H	Winter	296	0.02	<0.01	0.03
	KS/STF-BT009-89H	Winter	286	<0.01	<0.01	0.02

¹ Result of a single seed treatment application at approximately 0.5 oz ai/100 lbs seed.

² Straw samples were collected at earliest harvest.

³ Residues with reported value of <0.01 are assigned a value of 0.01 for the purpose of calculating the total residue.

Table 2. Barley Straw Residue Data - MRID No. 426963-08¹

Matrix	Location/Field Trial ID	Variety	PHI (days) ¹	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ²
Straw	MN/251-BT010-89H	Spring	83	0.05 0.05	<0.01 <0.01	0.06 0.06
	ND/251-BT011-89H	Spring	87	<0.01	<0.01	0.02
	ID/452-BT012-89H	Spring	110	<0.01	0.01	0.02
	WA/454-BT014-89H	Spring	108	0.01	<0.01	0.02
	KS/STF-BT016-89H	Winter	282	<0.01	<0.01	0.02

¹ Result of a single seed treatment application at approximately 0.5 oz ai/100 lbs seed.

² Straw samples were collected at earliest harvest.

³ Residues with reported value of <0.01 are assigned a value of 0.01 for the purpose of calculating the total residue.

Table 3. Oats Straw Residue Data - MRID No. 426963-09¹


Matrix	Location/Field Trial ID	PHI (days) ¹	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ²
Straw	MN/251-BT-017-89H	83	0.02	<0.01	0.03
	IA/255-BT018-89H	92	<0.01	<0.02	0.02
	NY/758-BT019-89H	114	<0.01	<0.01	0.02
	WI/851-BT020-89H	98	0.03	0.02	0.05
	IN/HIN-BT021-89H	107	<0.01	<0.01	0.02
	KS/STF-BT022-89H	122	<0.01	0.02	0.03

¹ Result of a single seed treatment application at approximately 0.5 oz ai/100 lbs seed.

² Straw samples were collected at earliest harvest.

³ Residues with reported value of <0.01 are assigned a value of 0.01 for the purpose of calculating the total residue.

CBTS notes that these residue data were previously reviewed in our 11/4/93 memorandum and

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were the basis of our recommendation to increase the tolerances for wheat straw, barley straw and oats straw.

CBTS concludes that the geographic representation of the available wheat, barley and oats straw residue data is adequate to support the requested tolerance increase.

The maximum residue level reported for wheat straw was 0.15 ppm. Of the 19 field trials reported, only one trial contained a residue level greater than the 0.1 ppm established triadimenol wheat straw tolerance. However, in our review of the submitted field trials, we could find no evidence to support the exclusion of this data point as an outlier. Since CBTS considers data generated on wheat translatable to both barley and oats, CBTS concludes that the cited residue data support an increase in the established tolerance from 0.1 ppm to 0.2 ppm for residues of triadimenol and its butanediol metabolite in/on wheat straw, barley straw and oats straw.

General Tolerance Consideration

In our review dated 11/4/93, CBTS addressed issues related to proposed use pattern, impurities in the technical product, analytical methods, metabolism and storage stability. We continue to find that there are no outstanding deficiencies with respect to these issues which would preclude an increase in the wheat, barley and oats straw tolerance as requested in this petition.

Other Considerations

The International Residue Limit Status Sheet is attached. As indicated on the attachment, Codex currently regulates the parent compound, triadimenol only. A Codex limit of 5 ppm for residues of triadimenol has been proposed (Step 6) for wheat straw and barley straw. A Codex limit of 5 ppm has been proposed (Step 3) for residues of triadimenol in/on oats straw. There are no Canadian or Mexican limits for this chemical or its metabolite.

Due to the difference in the tolerance expression, as well as the tolerance levels, compatibility between U.S. and Codex tolerances is not possible at this time.

cc: circ., RF, Triadimefon List B File, Triadimenol SF, PP#4F4320, DDavis.
H-7509C:CBTS:DSD:CM#2:Rm804:305-7085:dd:3/4/94.
RDI:SecHd:RSQuick:3/4/94:BrSrSc:RALoranger:3/4/94:BrCh:DFEdwards:3/7/94.
Disk:DSD-2 File:BAYTAN2.WBO