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

AUG 3 1993

MEMORANDUM:

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Thiabendazole, Reregistration. Magnitude of the Residue in Sweet Potato (MRID No. 42660301), Potato, and Potato Processed Commodities (MRID No. 42660302). CBRS No. 11601. DP Barcode No. D189323.

FROM: John Abbotts, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

THRU: Francis B. Suhre, Section Head
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

TO: Jay Ellenberger, Chief
Accelerated Reregistration Branch
Special Review and Reregistration Division [H7508W]

and Cynthia Giles-Parker, PM 22
Fungicide-Herbicide Branch
Registration Division [H7505C]

Attached is a review of residue chemistry data for magnitude of the residue in sweet potato, potato, and potato processed commodities, submitted by registrant Merck and Company, Inc., in response to Phase 4 Review. This information was reviewed by Acurex Corporation under supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

Note to RD PM: A copy of the review is being provided to RD because of the potential for treatment at registered rates to result in residues in excess of the existing tolerance.

The review concluded that additional data are required before the residue study and the processing study can be considered acceptable. Even with the deficiencies identified, however, the available data indicate that treatment at registered rates may result in residues in excess of the existing tolerance for sweet potato.

If you need additional input please advise.

cc:Circ, Abbotts, RF, Thiabendazole List B File, SF, Acurex
RDI:FBSuhre:7/29/93:EZager:8/2/93
H7509C:CBII-RS:JAbbotts:CM-2:Rm805A:305-6230:8/2/93
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THIABENDAZOLE
(Chemical Codes 060101 & 060102)
(CBRS No. 11601; DP Barcode D189323)

TASK 2B

Phase 5 - Reregistration Review
Residue Chemistry

May 28, 1993

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Environmental Corporation
Eastern Regional Operations
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709

THIABENDAZOLE

(Chemical Codes 060101 & 060102)

(CBRS No. 11601; DP Barcode D189323)

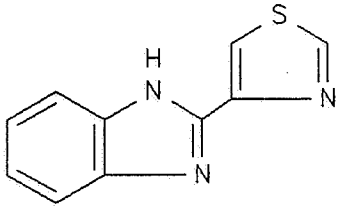
PHASE 5 - REREGISTRATION REVIEW RESIDUE CHEMISTRY

Task 2B

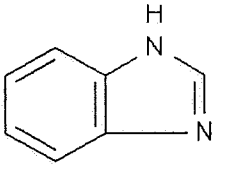
BACKGROUND

The Thiabendazole Phase 4 review dated 2/91 required data depicting residues of thiabendazole and its regulated metabolites in or on potatoes and sweet potatoes following seed tuber/root and postharvest treatments at 1x maximum use rates. Processing data were also required for potatoes. In response, Merck & Co. Inc. (1993; MRIDs 42660301 and 42660302) has submitted magnitude of the residue data for potatoes and sweet potatoes, and processing data for potatoes. These data are reviewed here to determine their adequacy in fulfilling residue chemistry data requirements. The Conclusions and Recommendations stated in this review pertain only to thiabendazole residues in or on potatoes, sweet potatoes, and potato processed commodities.

The nature of the residue in plants and animals is adequately understood. The residues of concern in plants are thiabendazole, BNZ, and BNZ conjugates (CBRS 8192, 3/11/92, L. Cheng). The residues of concern in animals are thiabendazole, 5-OH thiabendazole (free and conjugates), and BNZ (Memo, 2/14/92, L. Cheng). Methods are available for determining residues of thiabendazole per se in or on plant commodities and are listed in PAM, Vol. II, as Methods I, A, B, and C. A method is available for determining residues of thiabendazole and 5-OH-thiabendazole in milk, and is listed in PAM, Vol. II, as Method D.



Thiabendazole



Benzimidazole (BNZ)

Tolerances for residues of thiabendazole (2-(4-thiazolyl)benzimidazole) in or on raw and processed plant commodities are currently expressed in terms of thiabendazole per se [40 CFR §180.242(a), §185.5550, and §186.5550(a)], and tolerances in animal commodities are expressed in terms of the combined residues of thiabendazole and its metabolite, 5-hydroxy-thiabendazole, [40 CFR §180.242(b)]. CBRS has recommended that BNZ and its conjugates be added to the tolerance definitions for plant commodities (CBRS 8192, 3/11/92, L. Cheng).

Codex MRL and U.S. tolerance definitions for thiabendazole residues are both currently expressed in terms of thiabendazole per se; however, the U.S. tolerance (10 ppm) and Codex MRL (CXL) (5 ppm) for potatoes are not compatible, and the Codex MRL is specifically for washed tubers. In addition, once the U.S. tolerance expression is expanded to include residues of BNZ and its conjugates, the U.S. and Codex MRL definitions will no longer be compatible. Because Codex MRLs do not exist for sweet potatoes and potato processed fractions, there are no questions regarding compatibility with the U.S. tolerances for these commodities.

CONCLUSIONS

1a. The submitted method validation data indicate that method S.A.P. 500-P-021 is adequate for collecting data on residues of thiabendazole and free benzimidazole (BNZ) in or on potatoes, and for collecting data on residues of thiabendazole per se in potato processed commodities.

1b. Tolerance enforcement methodology capable of quantifying BNZ and its conjugates must be developed. Methods proposed for enforcement must undergo independent laboratory validation prior to being submitted for EPA lab validation. Until analytical methodology is validated for the ability to detect BNZ and its conjugates in plant commodities, judgment on residues of BNZ and its conjugates will be reserved.

2a. The storage stability data indicate that residues of thiabendazole and BNZ are stable for at least 3 months in or on whole potatoes and wet potato peel stored at -23 °C. Additional storage stability data for residues of thiabendazole and BNZ are required reflecting the storage intervals and conditions of all treated samples.

2b. The storage stability data also indicate that residues of BNZ are stable in wet peel samples prepared for analysis for up to three months (102 days) before actual analysis. The registrant must describe the physical condition, the type of container, and the storage temperature for the wet peel sample preparations stored for that interval.

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3. Residues of thiabendazole per se in or on potatoes treated at the maximum labeled rate did not exceed the established 10 ppm tolerance. These data are adequate for residues of thiabendazole per se, pending submission of supporting storage stability data, and provided that the registrant amends all pertinent product labels to specify a minimum interval of 30 days between post-harvest applications.

4a. Residues of thiabendazole in or on sweet potatoes treated at the maximum labeled rate exceeded the established 0.02 ppm tolerance.

4b. No data were submitted depicting residues of BNZ in or on sweet potatoes. Residue data on BNZ and its conjugates are required.

4c. Storage stability data in support of residue data on sweet potatoes were not provided.

5. The potato processing data indicate that residues of thiabendazole per se concentrated by 16.6x in dry peel, and therefore in processed potato waste as well. However, an appropriate level for a food additive tolerance cannot be determined until the outstanding data for residues of BNZ and its conjugates, and the outstanding storage stability data, have been received and evaluated.

RECOMMENDATIONS

Additional data are necessary to upgrade the present submission to an acceptable status. Conclusions 2a, 2b, 3, 4b, 4c, and 5 should be resolved. In accordance with Conclusion 1b, judgment is reserved on residue data on benzimidazole (BNZ) and its conjugates, pending validation of a method to detect these residues. If the registrant wishes to support the current tolerance in sweet potato by lowering the application rate, field tests must be conducted at 1x the intended rate, and samples must be analyzed for thiabendazole and BNZ and its conjugates. In addition, all current and required data must be adequately supported by storage stability data.

Even with the deficiencies identified in the sweet potato residue study (Conclusions 4b and 4c), the current data indicate that treatment at registered rates may lead to residues which exceed the existing tolerance for sweet potato of parent thiabendazole only at 0.02 ppm.

DETAILED CONSIDERATIONS

Reregistration Requirements

Phase 4 Review (2/21/91, C.L. Olinger) required data on the nature of the residue in plants, residue data from field trials on potatoes and sweet potatoes, and processing data on potatoes. Data depicting residues of thiabendazole and the regulated metabolites in or on potatoes must be submitted. A representative formulation must be applied post-harvest

twice, the first application should be a drench at 1.2 lb ai/100 gal and the second should be a 20 sec dip at 0.12 lb ai/100 gal. Seed tubers should be treated similarly, except the second treatment should be at 1.2 lb ai/100 gal. Tubers subjected to the first treatment scheme should be analyzed directly. Residue data should be collected on tubers grown from the treated seed pieces grown in ID, WA, ND, ME, CO, and CA. A processing study must be conducted for potatoes. Potatoes bearing detectable residues of the parent and the regulated metabolites should be processed into peel (dry and wet), granules, and chips to determine the residue concentration factor(s). If the potatoes are treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the RAC, then processing studies are not required.

Data depicting residues of thiabendazole and the regulated metabolites in or on sweet potato must be submitted. A representative formulation must be applied post-harvest to seed roots at planting as a 2-3 min dip at a rate of 3.17 lb ai/100 gal. Residue data should be collected from tubers grown from the treated seed roots in CA, LA, NC, TX, GA/MS, and NJ, which represent the major sweet potato production regions.

Review of plant metabolism studies recommended that the residues of concern in plants were thiabendazole and benzimidazole (BNZ) and its conjugates; registrant was required to develop a method capable of measuring BNZ and its conjugates (CBRS 8192, 3/11/92, L. Cheng). Subsequent review of residue data submitted for post-harvest treatment of pome fruits concluded that after adequate analytical methodology is developed that is capable of detecting BNZ and conjugates, residue data for BNZ must be submitted (CBRS 10954, 4/15/93, R.B. Perfetti).

Residue Analytical Methods

Merck & Co. Inc. (1993; MRIDs 42660301 and 42660302) submitted analytical method descriptions for determining the residues of thiabendazole per se in or on whole potatoes and potato flakes, and for determining the residues of BNZ in or on whole potatoes. Residues of both compounds were determined using Merck Standard Assay Procedure 500-P-021, a modification of Method C in PAM Vol. II. Briefly, samples are slurried with water, hydrolyzed on a steam bath using a mixture of sulfuric and hydrochloric acids, and digested overnight with diastase. Residues are extracted using ethyl acetate and are purified using a series of acid/base partitioning procedures. Residues of thiabendazole are determined spectrofluorometrically using an excitation wavelength of ~305 nm and an emission wavelength of ~360 nm; residues of BNZ are determined by HPLC using fluorescence detection. The registrant reported that the limits of detection (LOD) for thiabendazole are 0.02 ppm for whole potatoes and 0.01 ppm for potato flakes, and that the LOD for BNZ is 0.01 ppm for whole potatoes.

Method validation recoveries are shown in Table 1. Recoveries of thiabendazole were 84-109% from whole potatoes fortified at 0.05-10 ppm, and were 96-116% from potato flakes fortified at 0.025-0.25 ppm. Recoveries of BNZ were 91-110% from whole potatoes

fortified at 0.02 and 0.05 ppm. The registrant did not submit method validation data for BNZ in potato flakes. Sample calculations were provided for both compounds. A standard fluorescence spectrum was provided for thiabendazole, and representative HPLC chromatograms were provided for a whole potato control and a control sample spiked at 0.02 ppm with BNZ and at 5 ppm with thiabendazole.

Table 1. Method validation recoveries for residues of thiabendazole and BNZ generated using method S.A.P. 500-P-021.

Matrix	Thiabendazole		BNZ	
	Fortification level (ppm)	% Recovery[a]	Fortification level (ppm)	% Recovery[b]
Whole potatoes	0.05	93	0.02	93-110
	0.2	109	0.05	91-97
	0.5	92		
	1	88-95		
	5	84, 92		
	10	94		
Potato flakes	0.025	116	--	--
	0.05	104		
	0.1	103		
	0.25	96		

[a]Average recovery from duplicate aliquots of a single fortified sample, except 3 samples were fortified at 1 ppm and 2 samples were fortified at 5 ppm. Recoveries were corrected for apparent thiabendazole residues of 0.010 ppm in or on a single potato control sample, and of 0.006 ppm in or on a single potato flakes control sample.
[b]Recovery from duplicate injections of two samples fortified at each level. Apparent residues of BNZ were reported to be <0.01 ppm in or on a single potato control sample.

Concurrent method recoveries of thiabendazole from storage stability analyses were 91-103% from potatoes fortified at 0.2 ppm, and were 101-111% from wet peel samples fortified at 0.5 ppm (four samples each). Concurrent method recoveries of BNZ from storage stability analyses were 95-116% from potatoes fortified at 0.05 ppm, and were 94-108% from wet peel samples fortified at 0.1 ppm (four samples each).

Conclusion 1a: The submitted method validation data indicate that method S.A.P. 500-P-021 is adequate for collecting data on residues of thiabendazole and free benzimidazole (BNZ) in or on potatoes, and for collecting data on residues of thiabendazole per se in potato processed commodities.

Conclusion 1b: Tolerance enforcement methodology capable of quantifying BNZ and its conjugates must be developed. Methods proposed for enforcement must undergo independent laboratory validation prior to being submitted for EPA lab validation. Until analytical

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methodology is validated for the ability to detect BNZ and its conjugates in plant commodities, judgment on residues of BNZ and its conjugates will be reserved.

Storage Stability Data

Merck & Co. Inc. (1993; MRIDs 42660301 and 42660302) submitted 3-month data depicting the storage stability of thiabendazole and BNZ in or on whole potatoes and wet peel. The registrant indicated that these are preliminary data from a 24-month storage stability study. Two samples each of potatoes and wet peel were fortified with thiabendazole and BNZ and were processed for analysis at zero time (0-1 day), and a second set of fortified potato and wet peel samples was stored at -23 °C for approximately 3 months (whole potatoes, 104 days; wet peel, 94 days). Fortification levels and recoveries of thiabendazole from stored and freshly fortified samples are shown in Table 2.

Table 2. Storage stability of thiabendazole and BNZ in or on whole potatoes, and of thiabendazole in wet peel.

Commodity	Storage interval (months)	Thiabendazole			BNZ		
		Fortification level (ppm)	% Recoveries[a]		Fortification level (ppm)	% Recoveries[a]	
			Stored samples	Fresh fortification		Stored samples	Fresh fortification
Whole potatoes	0	0.2	91-107	91-102	0.05	98-111	95-116
	3	0.2	98-103	96-103	0.05	92-103	100-104
Wet peel	0	0.5	106-108	101-110	0.1	100-119	100-108
	3	0.5	98-109	103-111	0.1	93-96	94-101

[a]Recoveries from two stored and two freshly fortified samples per interval per commodity, corrected by the registrant for apparent residues in or on control samples. Apparent residues of thiabendazole were 0.010 and <0.01 ppm in or on the zero-time and 3-month potato controls, respectively, and were 0.009 and 0.02 ppm in the zero-time and 3-month wet peel controls, respectively. Apparent residues of BNZ were reported to be nondetectable (<0.01 ppm) in or on the zero-time and 3-month potato controls.

The intervals between preparing the storage stability samples for analysis and the actual analyses for thiabendazole were 0-1 day. The intervals between sample preparation and the actual analyses for BNZ were 4 and 8 days for the whole potato samples, and were 7 and 102 days for the wet peel samples.

For the current residue studies, treated samples were stored frozen (≤ -20 °C) for 574-724 days from time of last treatment (potatoes), harvest (sweet potatoes), or processing until the analysis for thiabendazole. The samples used for processing were stored fresh for an additional 10 days at 6-9 °C prior to processing.

Conclusion 2a: The storage stability data indicate that residues of thiabendazole and BNZ are stable for at least 3 months in or on whole potatoes and wet potato peel stored at -23 °C. Additional storage stability data for residues of thiabendazole and BNZ are required reflecting the storage intervals and conditions of all treated samples.

Conclusion 2b: The storage stability data also indicate that residues of BNZ are stable in wet peel samples prepared for analysis for up to three months (102 days) before actual analysis. The registrant must describe the physical condition, the type of container, and the storage temperature for the wet peel sample preparations stored for that interval.

Magnitude of the Residue in Plants

Potatoes. A tolerance of 10 ppm has been established for residues of thiabendazole per se in or on potatoes (pre- and post-harvest) [40 CFR §180.242(a)]. CBRS has recommended that the tolerance definition in plants be expanded to include residues of BNZ and its conjugates.

A REFS search dated 5/27/93 identified two Merck & Co. Inc. products for use on potatoes, a 3.8 lb/gal FlC formulation (EPA Reg. No. 618-75) and a 89% G formulation (EPA Reg. No. 618-92). The FlC formulation is also the parent product for SLN ME90000300 for use on potatoes. The FlC formulation is registered for a mist application to potatoes entering storage, at a rate of 0.0125 lb ai/2000 lb tubers, followed after an unspecified storage interval by a mist application at the same rate or a 20-second dip application at 0.0125 lb ai/gal water. An application may also be made to seed tubers prior to cutting.

Merck & Co. Inc. (1993; MRID 42660302) submitted data from four tests conducted in ID, MI, ME, and WA (1 test each) depicting the residues of thiabendazole in or on unwashed potato tubers following a total of three aqueous mist applications, each delivered at a rate of 0.0125 lb ai/2000 lb tubers. Seed tubers were misted, then cut into seed pieces and planted the same day (2 tests), 3, or 7 days after treatment. Mature tubers were harvested 115-138 days following application, were misted within one day of harvest, and were put into fresh storage (1-24 °C). After 30 days, the tubers received a final mist application, and four replicate samples per test were collected and frozen within 1 hour of treatment. Samples were maintained in frozen storage (approximately -26 °C) for 574-621 days (19-20 months) prior to analysis using method S.A.P. 500-P-021. Residues of thiabendazole per se were 1.2-7.3 ppm in or on 16 treated samples (Table 3); apparent residues were <0.01-0.01 ppm in or on four replicate control samples from each test. The registrant stated that treated potatoes from all field trials were analyzed for BNZ, and that residues of BNZ were <0.01 ppm (nondetectable).

Table 3. Residues of thiabendazole in or on treated potato tubers following 3 applications at 0.0125 lb ai/2000 lb tubers.

Commodity	Test site (number)	Thiabendazole (ppm)[a]	Frozen storage interval, days
Potatoes	ID (3031)	1.2-1.9	574
	MI (3032)	2.8-5.5	579
	ME (3033)	2.6-4.2	581
	WA (3034)	6.0-7.3	610

[a]Average of duplicate aliquots of four replicate treated samples per range; residues not corrected for controls (all <0.01-0.01 ppm) or for concurrent method recovery (no concurrent recoveries generated).

Geographic representation is irrelevant because the postharvest applications, which are likely to result in the highest residues, are conducted indoors in a commercial setting and are followed by controlled temperature storage and shipping.

Conclusion 3: Residues of thiabendazole per se in or on potatoes treated at the maximum labeled rate did not exceed the established 10 ppm tolerance. These data are adequate for residues of thiabendazole per se, pending submission of supporting storage stability data, and provided that the registrant amends all pertinent product labels to specify a minimum interval of 30 days between post-harvest applications.

Sweet Potatoes. A tolerance of 0.02 ppm has been established for residues of thiabendazole per se in or on sweet potatoes (applied post-harvest to sweet potatoes intended only for use as seed) [40 CFR §180.242(a)]. CBRS has recommended that the tolerance definition in plants be expanded to include residues of BNZ and its conjugates.

A REFS search dated 5/27/93 identified two Merck & Co. Inc. products for use on sweet potatoes, a 3.8 lb/gal FlC formulation (EPA Reg. No. 618-75) and a 89% G formulation (EPA Reg. No. 618-92). The FlC formulation is registered for use on sweet potato seed roots as a 1-2 minute dip application, using a suspension containing 3.18 lb ai/100 gal water, followed immediately by planting. A restriction has been established that prohibits the use of treated sweet potato roots as food or feed.

Merck & Co. Inc. (1993; MRID 42660301) submitted data from four tests conducted in CA, GA, LA, and NC (1 test each) depicting the residues of thiabendazole in or on unwashed sweet potatoes following treatment of the seed roots prior to planting. Seed roots were dipped for 2 minutes in an aqueous suspension containing 3.18 lb ai/100 gal water (1x the maximum labeled rate), planted the same day in seed beds, and later transplanted into the field. Four replicate samples per test of mature roots were harvested 125-153 days following treatment, and were frozen within 1 hour of collection. The treated roots were stored at approximately -26 °C for 698-729 days (23-24 months) prior to analysis using method S.A.P. 500-P-021. Residues of thiabendazole per se were 0.006-0.027 ppm in or on 16 treated samples (Table 4); apparent residues were 0.005-0.009 ppm in or on 16 untreated

controls. Overtolerance residues were found in or on two samples (one each from the CA and GA tests).

The registrant stated that because residues of BNZ were <0.01 ppm (nondetectable) in or on all treated potato samples (MRID 42660302; discussed under "Potatoes" above), no analyses for BNZ were performed for sweet potatoes.

Geographic representation is adequate. The test states of CA(12%), GA(6%), LA(26%), and NC(38%) accounted for approximately 82% of U.S. sweet potato production in 1990 (Agricultural Statistics 1991, p. 164).

Table 4. Residues of thiabendazole per se in or on sweet potato roots following a 2 minute pre-planting dip in an aqueous suspension of thiabendazole (3.18 lb ai/100 gal water).

Commodity	Test site (number)	Thiabendazole (ppm)[a]	Frozen storage interval, days
Sweet potatoes	CA (3037)	0.021, 0.020 0.019, 0.018 0.013, 0.013 0.011, 0.012	716
	GA (3038)	0.027, 0.014 0.008, 0.007 0.006, 0.006 0.006, 0.006	724
	LA (3039)	0.008, 0.009 0.008, 0.008 0.008, 0.008 0.007, 0.008	716
	NC (3040)	0.006, 0.007 0.006, 0.006 0.008, 0.008 0.012, 0.007	698

[a]Duplicate aliquots of four replicate samples per test; not corrected for controls (0.005-0.009 ppm) or for concurrent method recovery (no concurrent recoveries generated).

Conclusion 4a: Residues of thiabendazole in or on sweet potatoes treated at the maximum labeled rate exceeded the established 0.02 ppm tolerance.

Conclusion 4b: No data were submitted depicting residues of BNZ in or on sweet potatoes. Residue data on BNZ and its conjugates are required.

Conclusion 4c: Storage stability data in support of residue data on sweet potatoes were not provided.

Recommendation: Even with the deficiencies identified in the sweet potato residue study (Conclusions 4b and 4c), the current data indicate that treatment at registered rates may lead to residues which exceed the existing tolerance for sweet potato of parent thiabendazole only at 0.02 ppm.

Magnitude of the Residue in Processed Foods/Feeds

Potato Processed Commodities. A tolerance of 30 ppm has been established for residues of thiabendazole in or on potato processing waste (pre- and post-harvest) [40 CFR §186.5550(a)]. CBRS has recommended that the tolerance definition in plants be expanded to include residues of BNZ and its conjugates.

Merck & Co. Inc. submitted data (1993; MRID 42660302) from tests conducted in WA depicting residues of thiabendazole per se in or on potato tubers and processed commodities (chips, flakes, wet peel, dry peel) following a total of three aqueous mist applications, each delivered at a rate of 0.0125 lb ai/2000 lb tubers (1x). Seed tubers were misted, cut into seed pieces, and planted the same day. Mature tubers were harvested, misted the same day, and placed into fresh storage for 30 days. Following the final mist application, a composite sample was collected and delivered to the processing facility within 2.5 hours of treatment. Samples were stored fresh (6-9 °C) for 10 days until being processed using simulated commercial procedures. The fractions were then frozen and maintained in frozen storage ($\leq$ -20 °C) for 590-606 days (19-20 months) prior to analysis using method S.A.P. 500-P-021. Residues of thiabendazole per se found in or on processed fractions are shown in Table 5; apparent residues in or on the control samples were <0.01 ppm (unwashed tubers, washed tubers, wet peel), <0.04 ppm (flakes), and <0.2 ppm (dry peel, chips).

The registrant stated that the treated dry peel was analyzed for BNZ, and that residues of BNZ were <0.01 ppm (nondetectable). However, no data were submitted to support this statement.

Concentration factors for residues of thiabendazole per se are calculated in Table 5. Residues of thiabendazole per se concentrated 16.6x in dry peel. The concentration factors may change when residues of BNZ and its conjugates, and the required storage stability data, are taken into account.

Table 5. Residues of thiabendazole per se in or on potato tubers and processed commodities.

Commodity	Thiabendazole (ppm)[a]	Concentration factor	Frozen storage interval (days)[b]
Whole tubers (RAC)	6.5	--	600
Washed tubers	2.2	n/c[c]	590
Flakes	0.2	n/c	604
Chips	0.2	n/c	604
Wet peel	6.5	n/c	600
Dry peel	108	16.6x	606

[a]Average of duplicate aliquots from one sample. [b]Interval between dates of processing and analyses. RAC samples were stored fresh for an additional 10 days at 4-6 °C prior to processing. [c]n/c - no concentration.

It should be noted that Phase 4 Review (2/21/91, C.L. Olinger) required residue data on potato processed commodities granules, chips, wet peel, and dry peel. In addition, residue data are not required on processed potato waste, but feed additive tolerances for this commodity should be based on the maximum concentration factor observed for residues in or on granules, wet peel, or dry peel. According to the Potato Cultural Practices File, residue data on granules and flakes are expected to be similar. Both flakes and granules are derived from plant pulp and they have the same approximate moisture content (7%). Granules are the result of more processing steps than flakes, and the additional steps are more likely to reduce residues, compared to flakes, than increase them. Use of data on flakes to substitute for granules is therefore acceptable.

Conclusion 5: The potato processing data indicate that residues of thiabendazole per se concentrated by 16.6x in dry peel, and therefore in processed potato waste as well. However, an appropriate level for a food additive tolerance cannot be determined until the outstanding data for residues of BNZ and its conjugates, and the outstanding storage stability data, have been received and evaluated.

References

Citations for the MRID documents referenced in this review are presented below. Submissions reviewed in this document are indicated by shaded type.

42660301 Norton, J. (1993) The Determination of the Presence and Magnitude of Residues of the Fungicide Thiabendazole in Sweet Potatoes Grown from Seed Roots Treated with Mertect 340-F: Lab Project Number: 92851: 001-90-3037R: ASA-90-NC01. Unpublished study prepared by Agricultural Systems Associates and Merck Research Labs. 394 p.

42660302 Norton, J.; Armstrong, T. (1993) Determination of the Magnitude of the Residues of the Fungicide Thiabendazole in Potatoes Treated with Mertect 340-F by Mist Application: Lab Project Number: 93036: 001-90-3031R: SARS-90-ID-32. Unpublished study prepared by Stewart Agricultural Research Services, Inc. and Merck Research Labs. 658 p.

Agency Memoranda

CBRS No. None
Subject: Thiabendazole Livestock (Goat and Poultry) Metabolism. The Metabolism Committee Meeting Held on February 12, 1992.
From: L. Cheng
To: HED Metabolism Committee
Dated: 2/14/92
MRID(s): None

CBRS No. 8192
Subject: Thiabendazole Phase V Review. Metabolism Studies: Wheat, Soybean, and Sugar Beet.
From: L. Cheng
To: F. Rubis
Dated: 3/11/92
MRID(s): 41872901, -02, and -03

CBRS Nos. 8930, 8719
Subject: Thiabendazole. Phase V Review. Goat and Poultry Metabolism Studies.
From: L. Cheng
To: F. Rubis
Dated: 3/2/92
MRID(s): 42057901, 42011701