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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

MEMORANDUM

Date: November 17, 2005

Subject: Triadimenol. Summary of Analytical Chemistry and Residue Data for the

Tolerance Reassessment Eligibility Decision (TRED) Document.

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Executive Summary

Triadimenol, β -(4-chlorophenoxy)- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, is a systemic fungicide registered for use in the United States as a seed treatment for barley, corn, cotton, oats, rye, sorghum, and wheat. Additionally, an import tolerance on bananas has been established. Triadimenol end-use products are marketed in the U.S. under the trade name Baytan®. The reregistration of triadimenol is being supported by Bayer CropScience (Bayer), the basic producer. The triadimenol formulations registered for food/feed uses include wettable powder (WP), flowable concentrate (FIC), emulsifiable concentrate (EC), and soluble concentrate (SC) formulations.

Tolerances are established for residues of triadimenol and 1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol (KWG 1342; calculated as triadimenol) in/on various plant commodities [40 CFR §180.450(a)]. The established tolerances for plant commodities range from 0.01 ppm (sorghum grain and fodder) to 2.5 ppm (green forage of oats, rye, and wheat). Tolerances are established for residues of triadimenol and its metabolites containing the chlorophenoxy moiety (calculated as triadimenol) in/on livestock commodities at 0.01 ppm (milk, and poultry commodities) and 0.1 ppm (fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep).

Triadimenol and its butanediol metabolite (KWG 1342) are also regulated as metabolites of the fungicide triadimefon (40 CFR §180.410). In addition, 40 CFR §180.3(d)(13) specifies that where tolerances are established for residues of both 1-(4- chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone (triadimefon) and triadimenol including its butanediol metabolite in or on the same raw agricultural commodity and its products thereof, the total amount of such residues shall not yield more residue than that permitted by the higher of the two tolerances. Currently, triadimefon and triadimenol do not share any uses, so 40 CFR §180.3(d)(13) should be deleted.

The reregistration requirements for plant metabolism have not been fulfilled. No metabolism studies with triadimenol have been submitted; however, metabolism studies with triadimefon have been received and reviewed. The Health Effects Division (HED) has examined the results of these studies and determined that the triadimefon residues of concern in/on apples, grapes, pears, pineapples, and raspberries for tolerance expression are triadimefon and triadimenol and for risk assessment are triadimefon, triadimenol, KWG 1323 [1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone], and KWG 1342 (S. Ary, D314742, 11/23/2005). Of these compounds, triadimenol and KWG 1342 are currently regulated for plant commodities.

HED has determined that translation of metabolism data from triadimefon to triadimenol is not appropriate for the existing uses on cereal grains and cotton. The metabolism studies with triadimefon were conducted using a foliar application and triadimenol is used only as a seed treatment. Additionally, in the submitted triadimenol seed treatment wheat study, residues in grain were not identifiable due to the low activity found in wheat grain. Therefore, HED concludes that the nature of the residue in cereal grains and cotton is not adequately understood; however, based on chemical structure and the probable metabolic pathway of triadimenol, the residues of concern for tolerance expression and risk assessment are likely to be triadimenol,

KWG 1342, and KWG 1732 in/on cereal grains (barley, corn, oats, rye, and wheat) and cotton. Separate metabolism studies with triazole-¹⁴C and phenyl-¹⁴C labeled triadimenol applied as a seed treatment to corn or wheat and cotton should be conducted to confirm the residues of concern. The residues of concern for tolerance expression and risk assessment for bananas are triadimenol and KWG 1342.

Additionally, the Agency does have concern about the potential toxicity of 1,2,4-triazole and two conjugates, triazole alanine and triazole acetic acid, which are metabolites common to most of the triazole fungicides. To support the extension of existing and granting of new parent triazole-derivative fungicide tolerances, the Agency will be conducting a human-health assessment for aggregate exposure to 1,2,4-triazole.

The reregistration requirements for livestock metabolism are fulfilled based on acceptable goat and poultry metabolism studies submitted to support reregistration of triadimefon. HED has determined that the residues of concern for tolerance expression and risk assessment in livestock are triadimenol and KWG 1342.

The Pesticide Analytical Manual (PAM) Vol. II does not contain a listing for triadimenol (February 1997 Index). However, the methods listed for triadimefon can be used for the determination of triadimenol, KWG 1323, KWG 1342, and KWG 1732. PAM lists two gas chromatography with mass spectrometry detection (GC/MS) methods (Methods I and II) for the determination of triadimenol and its free and conjugated metabolites in plant and livestock commodities. Both methods are common moiety methods. The reported limit of quantitation (LOQ) is 0.05 and limit of detection (LOD) is 0.01 ppm for both methods.

In conjunction with triadimefon reregistration, Bayer has proposed a GC/MS method (Report No. 106549) for enforcement of tolerances for residues of triadimefon, triadimenol, KWG 1342, KWG 1323, and KWG 1732 in/on barley, corn, cotton, oat, rye, and wheat commodities. The method has been successfully radiovalidated and has undergone independent laboratory validation. The reported method LOQ is 0.05 ppm for each analyte in cereal grains and 0.02 ppm in each analyte in cotton. Additionally, a GC method using a nitrogen phosphorus detector (NPD; Report No. 80488) is available for determination of residues of triadimenol, KWG 1342, and KWG 1323 and is adequate for the enforcement of the banana tolerance. The method has undergone a successful Agency method validation on tomatoes and was submitted to the FDA for publication in PAM Vol. II. The reported method LOQ is 0.01 ppm for each analyte.

The reregistration requirements for multiresidue method testing for residues of triadimenol, KWG 1342, and KWG 1732 are satisfied.

The reregistration requirements for storage stability data are not satisfied for field corn, sweet corn, cotton, and wheat forage, hay, straw, and processed commodities pending the results from the requested metabolism studies.

The reregistration requirements for data depicting the magnitude of triadimenol residues of concern in meat, milk, poultry, and eggs have been fulfilled. Acceptable ruminant and poultry feeding studies have been submitted and evaluated. Triadimenol is not registered for use as a direct livestock treatment. The nature of the residue in livestock is adequately defined for the

current uses. HED concludes that the supported uses on barley, corn, cotton, oats, rye, and wheat result in a 40 CFR §180.6(a)(3) situation for ruminant commodities; i.e., there is no reasonable expectation of finite residues in ruminant commodities. Therefore, additional data on the transfer of residues to meat, milk, poultry, and eggs are not required and all tolerances for livestock commodities should be revoked pending results from the requested corn and wheat metabolism studies. If registration on additional commodities and livestock feed items are requested, then triazole and phenyl-labeled livestock metabolism studies would be required. Such data may, in turn, trigger the need for magnitude of the residue (feeding) studies in livestock.

The reregistration requirements for magnitude of the residue in/on bananas are fulfilled. Additional field trials conducted with field corn (forage, grain, stover), sweet corn (forage, K+CWHR, grain, and stover), cotton (undelinted seed and gin byproducts), and wheat (forage, grain, hay, and straw) are required pending the results from the requested metabolism studies.

The reregistration requirements for magnitude of the residue in the processed commodities of field corn and cotton have been fulfilled. A wheat processing study conducted with triadimenol applied to wheat as a seed treatment should be submitted once the requested wheat metabolism studies have been submitted and reviewed.

No data pertaining to confined/field accumulation of triadimenol residues in rotational crops have been submitted; however, confined rotational crop data for triadimefon have been submitted and translated. The reregistration requirements for accumulation in rotational crops are fulfilled, pending submission of the requested wheat and corn triazole labeled metabolism studies for final determination of the metabolites of concern. HED has concluded that limited field rotational crop studies for triadimenol must be submitted.

A general summary of residue chemistry deficiencies are listed below; details of data requirements are listed in Table 5.

Regulatory Recommendations and Residue Chemistry Deficiencies

- Separate metabolism studies with triazole-¹⁴C and phenyl-¹⁴C labeled triadimenol applied as a seed treatment to wheat or corn and cotton should be conducted to confirm the residues of concern.
- Storage stability data for triadimenol, KWG 1342, and KWG 1732 in/on field corn, sweet corn, cotton, and wheat processed commodities are required pending the results from the requested metabolism studies. Storage stability data for KWG 1732 in/on wheat forage, hay, and straw are required pending the results from the requested metabolism studies.
- Crop field trial data depicting residues of triadimenol, KWG 1342, and KWG 1732 in/on field corn (forage, grain, stover), sweet corn (forage, K+CWHR, grain, and stover), cotton (undelinted seed and gin byproducts), and wheat (forage, grain, hay, and straw) grown from seed treated at the maximum rate are required pending the results from the requested metabolism studies.

- A wheat processing study conducted with triadimenol applied to wheat as a seed treatment should be submitted once the requested corn or wheat metabolism studies have been submitted and reviewed.
- Limited field rotational crop studies for triadimenol must be submitted pending the results from the requested metabolism studies.

Background

Triadimenol was first registered after 1984, and was not subject to FIFRA '88. Therefore, there have been no previous comprehensive reregistration reviews of this chemical. This document presents an overall and up-to-date Residue Chemistry Science Assessment with respect to the reregistration of triadimenol. The PC Code and nomenclature of triadimenol are listed below in Table 1 and the physicochemical properties are listed in Table 2. The structure of triadimenol and metabolites of concern are presented in Table 3.

Table 1. Triadimenol Nomenclat	Cable 1. Triadimenol Nomenclature.					
Chemical structure	CI—OOOH					
Common name	Triadimenol					
Molecular formula	$C_{14}H_{18}CIN_3O_2$					
Molecular weight	295.77 g/mol					
IUPAC name	(1RS,2RS;1RS,2SR)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol					
CAS name	β -(4-chlorophenoxy)- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol					
CAS number	55219-65-3					
PC Code	127201					
Current supported food/feed sites	barley, cotton, corn, oats, rye, and wheat					

Table 2. Physicochemical Proper	Table 2. Physicochemical Properties of Triadimenol						
Parameter	Value	Reference					
Melting point/range	109-115°C	MRID 00125399					
Density at 20°C	1.22 g/mL	MRID 00125399					
Water solubility at 20°C	0.012 g/100g of water	MRID 00125399					
Solvent solubility at 20°C	Triadimenol is insoluble in aliphatic hydrocarbons. 1 to 5 g/100g of toluene 10 to 20 g/100g of methylene chloride 40 to 60 g/100g of cyclohexanone	MRID 00125399					
Vapor pressure at 20°C	less than 1 mPa	MRID 00125399					

Table 3. Chemical Names and Structures of Triadim	enol and Its Metabolites.
Common name and chemical name	Chemical structure
Triadimenol (KWG 0519) $ \beta \text{-}(4\text{-chlorophenoxy})\text{-}\alpha\text{-}(1,1\text{-dimethylethyl})\text{-}1\text{H-}1,2,4\text{-}triazole\text{-}}1\text{-ethanol} $	CI—O OH
KWG 1342 1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl- 1-(1H-1,2,4-triazol-1-yl)-2-butanol	CI—OOH NOH
Triadimefon 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone	CI—OOO
KWG 1323 1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl- 1-(1H-1,2,4-triazol-1-yl)-2-butanone	CI—OOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOO
KWG 1732 1-(4-chlorophenoxy)-1-(1H-1,2,4-triazol-1-yl)ethanoic acid	CI—OOOO

Summary of Science Findings

860.1200 Directions for Use

Product List

There are five Bayer and one Wilbur-Ellis Company end-use products containing the active ingredient triadimenol, which are registered for use on domestically grown food/feed crops as indicated in Table 4. In addition, there is one Section 18 registered to the Texas Department of Agriculture. There are no SLN registrations for use of triadimenol.

Table 4. Triadi	Γable 4. Triadimenol End-use Products (EPs) Registered.							
EPA Reg. No.	Formulation ¹	Registrant	Product Name					
264-742	25% WP	Bayer CropScience	Baytan® Seed Treatment Fungicide					
264-760	28.3% FIC	Bayer CropScience	Baytan® 2.6 FS Seed Treatment Fungicide					
264-939	5% EC	Bayer CropScience	Gustafson RTU®- Baytan®-Thiram Fungicide					
264-941	30% FIC	Bayer CropScience	Gustafson Baytan® 30 Fungicide					
264-980	13.33 SC	Bayer CropScience	Protege Allegiance Bayton® W.P. Fungicide					
2935-459	30% FIC	Wilbur-Ellis Company	Wilbur-Ellis Baytan® Flowable					

^{1.} WP=Wettable Powder, FIC=Flowable Concentrate, EC=Emulsifiable Concentrate, and SC=Soluble Concentrate.

Use Pattern Table

A comprehensive summary of triadimenol food/feed use patterns based on the product labels registered to Bayer, was prepared by the Biological and Economic Analysis Division (BEAD; dated 3/2/2005) and is presented in Appendix 1. A tabular summary of the residue chemistry science assessments for reregistration of triadimenol is presented in Table 5. The conclusions listed in Table 5 regarding the tolerance reassessment eligibility decision of triadimenol food/feed uses are based on the use patterns being supported by the basic producer, Bayer. When end-use product data call in's (DCIs) are developed (e.g., at issuance of the TRED), the Registration Division (RD) should require that all end-use product labels (e.g., MAI labels, special local needs (SLNs), and products subject to the generic data exemption) be amended such that they are consistent with the labels registered to the basic producer.

As indicated in the triadimenol use closure memorandum (J. Pates, 7/26/2004), Bayer is no longer supporting the use of triadimenol on sorghum and has intentions on deleting the use from all labels.

Table 5. Residue Chemistry Science As	ssessment for the Tolera	nce Reassessmer	nt of Triadimenol.
GLN Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200 Directions for Use	Not applicable (N/A)	No	See Appendix 1
860.1300 Plant Metabolism	N/A	Yes ¹⁰	42123401-42123403 ² , 42798901 ³ , 42853401 ^{4,5} , 92188025-92188033 ⁶
860.1300 Livestock Metabolism	N/A	No	42123404 ² , 42856801 ^{5,7} , 42864901 ^{5,8} , 43418301- 43418302 ⁹ , 92188034- 92188039 ⁶
860.1340 Residue Analytical Methods			
Plant commodities	N/A	No	PP#4F3148, 43870101 ¹¹ , 44041002 ¹¹ , 92188040 - 92188043 ⁶
Livestock commodities	N/A	No	43418303 ⁹ , 92188044- 92188048 ⁶
860.1360 Multiresidue Methods	N/A No		40969801 ¹² , 41976601 ¹³ , 43705401 ¹⁴
860.1380 Storage Stability Data			•
Plant/processed commodities	N/A	Reserved ¹⁵	41976602 ¹⁶ , 42857401 ¹⁷ , 44038901 ¹¹ , 44041001 ¹¹ 92188051-92188053 ⁶
Livestock commodities	N/A	No	4346240118
860.1400 Magnitude of the Residue - Water, Fish, and Irrigated Crops	None established	No	
860.1460 Magnitude of the Residue - Food Handling	None established	No	
860.1480 Meat, Milk, Poultry, and Eggs			
Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.01, milk; 0.1, fat, meat, and mbyp of cattle, goats, hogs, horses, and sheep [§180.450(b)]	No	92188054-921880556
Eggs and the Fat, Meat, and Meat Byproducts of Poultry	0.01, eggs, fat, meat, and mbyp [§180.450(b)]	No	92188056-921880576

Table 5. Residue Chemistry Science Ass	sessment for the Tolera	nce Reassessmer	nt of Triadimenol.
GLN Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
Cereal Grains Group			
Barley	0.05 [§180.450(a)]	Reserved ¹⁹	$00125407-00125409^{20}, 42696308^{21}$
Corn, field, grain and aspirated grain fractions	0.05, grain [§180.450(a)]	Reserved	00125407-00125409 ²⁰
Corn, pop	0.05 [§180.450(a)]	Reserved ²²	
Corn, sweet (K+CWHR)	0.05 [§180.450(a)]	Reserved	00125407-00125409 ²⁰
Oat	0.05 [§180.450(a)]	Reserved ¹⁹	00125407-00125409 ²⁰ , 42696309 ²¹
Rye	0.05 [§180.450(a)]	Reserved ¹⁹	00125407-00125409 ²⁰ , 42712101 ²¹
Sorghum, grain and aspirated grain fractions	0.01, grain [§180.450(a)]	No ²³	00125407-00125409 ²⁰
Wheat, grain and aspirated grain fractions	0.05, grain [§180.450(a)]	Reserved ²⁵	$00125407-00125409^{20}, 42712101^{21}$
Fodder, Forage, Hay, and Straw of Cereal	Grains Group		
Barley, hay and straw	0.2, straw [§180.450(a)]	Reserved ¹⁹	00125407-00125409 ²⁰ , 42696308 ²¹
Corn, field, forage and stover	0.05, forage and fodder [§180.450(a)]	Reserved	00125407-00125409 ²⁰
Corn, pop, stover	0.05 [§180.450(a)]	Reserved ²²	
Corn, sweet, forage and stover	0.05, forage and fodder [§180.450(a)]	Reserved	00125407-00125409 ²⁰
Oat, forage, hay, and straw	2.5, green forage; 0.2, straw [§180.450(a)]	Reserved ¹⁹	00125407-00125409 ²⁰ , 42696309 ²¹
Rye, forage and straw	2.5, green forage; 0.1, straw [§180.450(a)]	Reserved ¹⁹	00125407-00125409 ²⁰ , 42712101 ²¹
Sorghum, forage and stover	0.05, green forage; 0.01, fodder [§180.450(a)]	No ²³	PP#3F2854 ²⁴

Table 5. Residue Chemistry Science Assessment for the Tolerance Reassessment of Triadimenol.						
GLN Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹			
Wheat, forage, hay, and straw	2.5, green forage; 0.2, straw [§180.450(a)]	Reserved ²⁵	00125407-00125409 ²⁰ , 42712101 ²¹			
Miscellaneous Commodities						
Banana	0.2 [§180.450(a)]	No	40615201 ²⁶ , 41051401 ²⁷			
Cotton, seed and gin byproducts	0.02, seed; Reserved ^{19,28} 0.02, forage [§180.450(a)]		41242801 ²⁹			
860.1520 Processed Food/Feed						
Barley	None established	Reserved ³⁰				
Corn, field	None established	No	44519801 ³¹			
Cotton	None established	No	44519802 ³¹			
Oats	None established	Reserved ³⁰				
Rye	None established	Reserved ³⁰				
Wheat	None established	Reserved	44029301 ³² , 44519803 ³¹			
860.1650 Submittal of Analytical Reference Standards	N/A	Yes ³⁵				
860.1850: Confined Rotational Crops	N/A	No	42613301 ³³			
860.1900: Field Rotational Crops	None established	Reserved ³⁴				

^{1.} **Bolded** references were submitted in support of reregistration of triadimefon. Unbolded references were submitted in support of registration of triadimenol.

- 2. DP Barcode D174151, 9/23/92, C. Swartz.
- 3. DP Barcode D194719, 10/20/93, C. Swartz.
- 4. DP Barcode D194676, 11/3/93, S. Knizner.
- 5. EPA Memorandum, no DP Barcode, 12/9/93, S. Knizner.
- 6. Triadimefon Phase 4 Review, 1/31/91, S. Funk.
- 7. DP Barcode D194819, 11/2/93, S. Knizner.
- 8. DP Barcode D194786, 11/2/93, S. Knizner.
- 9. DP Barcode D208890, 12/16/94, S. Knizner.

- DP Barcode: 314891
- 10. Separate metabolism studies with triazole-¹⁴C and phenyl-¹⁴C labeled triadimenol applied as a seed treatment to corn or wheat and cotton should be conducted to confirm the residues of concern.
- 11. DP Barcodes D222403, D227497, and D227543, 7/13/00, J. Punzi.
- 12. CB Nos. 4887, 4888, 4889, and 4890, 2/23/89, E. Haeberer.
- 13. Forwarded to FDA for inclusion in PAM Vol. I (L. Edwards memo of 6/30/92).
- 14. Forwarded to FDA for inclusion in PAM Vol. I.
- 15. Storage stability data for KWG 1732 are only available for wheat grain. Storage stability data for triadimenol, KWG 1342, and KWG 1732 in/on field corn forage, grain, and stover; sweet corn forage, kernel plus cob with husks removed (K+CWHR), grain, and stover; cotton undelinted seed and gin byproducts are required pending the results from the requested metabolism studies. Storage stability data for KWG 1732 in/on wheat forage, hay, and straw are required pending the results from the requested metabolism studies. Samples from the required crop field trials should be stored using the conditions and intervals under which residues are known to be stable. Additional storage stability data will be required if samples are not stored under these conditions and intervals.
- 16. DP Barcodes D168542 and D178884, 12/22/92, S. Hummel.
- 17. DP Barcode D194783, 11/17/93, S. Knizner.
- 18. DP Barcode D210160, 2/23/95, S. Knizner.
- 19. Crop field trial data depicting residues of triadimenol, KWG 1342, and KWG 1732 in/on field corn (forage, grain, stover), sweet corn (forage, K+CWHR, grain, and stover), cotton (undelinted seed and gin byproducts), and wheat (forage, grain, hay, and straw) grown from seed treated at the maximum rate are required pending the results from the requested metabolism studies. No data depicting residues of KWG 1732 in/on barley, oat, and rye commodities are available. The requested crop field trial data for wheat may be translated to barley, oat, and rye commodities provided that a confirmatory study with one of these grains is conducted in a suitable growing region.
- 20. PP#3F2854, 8/1/83, A. Smith.
- 21. DP Barcode D189881, 11/3/93, D. Davis.
- 22. Data to support use on popcorn can be translated from field corn.
- 23. No data are available depicting triadimenol residues of concern in/on sorghum commodities grown from seed treated with triadimenol, however, the basic producer is no longer supporting the use on sorghum and will remove the use from all labels.
- 24. The tolerance for sorghum commodities was established under PP#3F2854
- 25. No data are available depicting the magnitude of residues of KWG 1732 in/on wheat commodities following treatment of the seed with triadimenol. Crop field trial data depicting residues of triadimenol, KWG 1342, and KWG 1732 in/on wheat grain, forage, hay, and straw grown from seed treated at the maximum rate must be submitted. Data for wheat aspirated grain fractions are not required because triadimenol is applied as a seed treatment.
- 26. CB No. 3926, 1/6/89, S. Malak.
- 27. CB No. 5221, 5/16/89, S. Malak.
- 28. As a result of changes in Table 1 of OPPTS 860.1000, crop field trial data for cotton gin byproducts must now be submitted.

- DP Barcode: 314891
- 29. DEB No. 5865, 3/12/90, L. Rodriguez.
- 30. A wheat processing study conducted with triadimenol applied to wheat as a seed treatment should be submitted once the requested wheat metabolism studies have been submitted and reviewed. Data to satisfy barley, oats, and rye may be translated from wheat.
- 31. DP Barcode D322304, 10/14/2005, S. Ary.
- 32. The registrant proposed translating data from a triadimefon wheat grain processing study; however, these data cannot be translated to triadimenol due to differences in the use patterns (seed treatment vs. late season foliar sprays) that are likely to impact the potential concentration of residues.
- 33. DP Barcode D186937, 11/3/93, S. Knizner.
- 34. Limited field rotational crop studies for triadimenol must be submitted.
- 35. Analytical reference standards must be replenished as requested by the Repository.

860.1300 Nature of the Residue - Plants

The reregistration requirements for plant metabolism have not been fulfilled. Two metabolism studies with triadimenol have been submitted and are currently under review by the Agency and are summarized below.

In the wheat study (Bayer Report No. 69209, 10/15/1980), wheat seeds were treated with [phenyl-14C]triadimenol at the currently registered rate of 0.5 oz ai/100 lbs of seed. In mature wheat straw, triadimenol accounted for 58% of the total radioactive residue (TRR), KWG 1342 accounted for 36% of the TRR, while triadimefon accounted for 6% of the TRR. Extraction of mature grain did not produce enough activity to unequivocally identify any metabolites in the grain. It is noted that 52% of the activity originally applied was recovered, the remaining was assumed to be lost as ¹⁴CO₂ due to microbiological degradation.

In the sugar beet study, (Bayer Study No. M1731125-0, 1/23/2003), sugar beets were treated with two foliar applications of [phenyl-14C]triadimenol at 137 g ai/ha per application using an EC 250 formulation. In mature roots, triadimenol accounted for 64% of the TRR, KWG 1342 accounted for 17.7% of the TRR, and a glucoside of triadimenol (HYA604) accounted for 5.3% TRR. In mature leaves, triadimenol was found at 73.1% TRR, two glucosides of triadimenol were found at a total of 15.9% TRR, and KWG 1342 at 2.6% TRR. In forage leaves, triadimenol accounted for 26% of TRR while its two glucosides accounted for a total of 56.3% TRR, and KWG 1342 was found at 2.8% TRR.

Additionally, metabolism studies conducted with triadimefon have been received and are summarized below. These studies were conducted with grapes, cucumbers, tomatoes, and wheat.

Cucumber and Tomato (MRID 42123401)

In the cucumber and tomato metabolism studies, seedlings were treated with [phenyl-¹⁴Cltriadimefon at approximately 1x the maximum rate for cucumbers. Selected plants were treated two additional times, beginning at fruit set. Metabolism of triadimefon in tomato and cucumber seedlings receiving a single foliar application appears to consist of rapid degradation of the parent, concomitant with an increase in triadimenol. Hydrolysis of water-soluble radiocarbon and foliage samples from cucumber seedlings released triadimefon and triadimenol, as well as low levels of KWG 1323 and KWG 1342. These additional metabolites were not detected in the tomato seedlings. Degradation of triadimefon in mature cucumber and tomato plants appeared to be similar to that in the seedlings, with minor differences. The fruit and foliage differed in their ability to metabolize the parent. In both tomato and cucumber fruit, the terminal degradation product was primarily triadimenol, while the foliage of both tomato and cucumber exhibited a more complex series of degradation products. In tomato, triadimefon and triadimenol account for 96.6% TRR one day after treatment, 88.1% TRR 7 days after treatment, 83.8% TRR 14 days after treatment, 80.0% TRR 21 days after treatment, and 75.7% TRR 28 days after treatment. Similar results were reported for cucumber. KWG 1732 was not identified in either tomatoes or cucumbers.

Grape (MRID 42123403)

In a grape metabolism study, mature fruit were harvested 56 days following treatment of an established vine with [phenyl-¹⁴C]triadimefon; immature fruit were harvested at various earlier intervals. A rapid decline in total radioactivity was observed, due to the volatility of triadimefon. The decline in the quantity of parent observed was accompanied by a buildup of the metabolite triadimenol. Triadimenol accounted for 55.6% of TRR in mature grapes while triadimefon was only detected at 1.1% TRR. The remainder of the identified radioactivity was comprised of KWG 1342 and its conjugates (15.5% TRR), triadimenol conjugates (5.6% TRR), and p-chlorophenol and its conjugates (6.2% TRR). KWG 1732 was not identified in the study.

Wheat (MRID 42853401)

Following foliar treatment of wheat with [phenyl-14C]triadimefon at a rate of 236 g ai/A, approximately 2x the maximum registered rate for wheat, the metabolite KWG 1732 was the major residue identified (35% TRR) in wheat grain; a glucoside of KWG 1342 was the other major residue identified (21% TRR) in wheat grain. Additionally, triadimefon accounted for 1% TRR, triadimenol accounted for 6% TRR and its glucoside was found at 6% TRR; p-chlorophenol was also identified at 5% TRR. In wheat forage, triadimefon was found at 31-74% TRR and triadimenol was found at 12-35% TRR; together they accounted for the majority of residues (66-86% TRR); p-chlorophenol and its glucoside were also identified, at 9-16% TRR. In wheat straw, triadimenol and its conjugates accounted for the majority of the radioactivity at 53% TRR and triadimefon accounted for only 1% TRR; p-chlorophenol and its conjugates and KWG 1342 and its conjugates were also identified, at 21% and 19% TRR, respectively.

The Health Effects Division (HED) has examined the results of these studies and determined that the triadimefon residues of concern in/on apples, grapes, pears, pineapples, and raspberries for tolerance expression are triadimefon and triadimenol and for risk assessment are triadimefon, triadimenol, KWG 1323, and KWG 1342 (S. Ary, D314742, 11/23/2005). Of these compounds, triadimenol and KWG 1342 are the compounds that are currently regulated for plant commodities. The chemical names and structures of these compounds are presented in Table 3.

HED has determined that translation of metabolism data from triadimefon to triadimenol is not appropriate for the existing uses on cereal grains. The metabolism studies with triadimefon were

conducted using a foliar application and triadimenol is used only as a seed treatment. In the submitted triadimenol wheat study, residues in grain were not identifiable due to the low activity found in wheat grain. Therefore, HED concludes that the nature of the residue in cereal grains is not adequately understood; however, based on chemical structure and the probable metabolic pathway of triadimenol, the residues of concern for tolerance expression and risk assessment are likely to be triadimenol, KWG 1342, and KWG 1732 in/on cereal grains (barley, corn, oats, rye, and wheat) and cotton. The wheat metabolism study conducted with triadimefon indicate that KWG 1732 is the major metabolite found in grain at 35% TRR and KWG 1342 at 21% TRR in grain. Triadimenol accounted for 12% TRR. It is also noted that the submitted wheat processing study conducted with triadimenol applied as a seed treatment identified quantifiable residues of KWG 1732. There have been no previous triazole labeled studies conducted with triadimenol applied as a seed treatment to commodities and data from the available soil metabolism studies conducted with triadimefon indicate that soil microbes metabolize the triazole fungicide to free triazole, which may be taken up into the plant. Separate metabolism studies with triazole-14C and phenyl-14C labeled triadimenol applied as a seed treatment to corn or wheat and cotton should be conducted to confirm the residues of concern.

The residues of concern for tolerance expression and risk assessment for bananas are triadimenol and KWG 1342, which are based on the available metabolism data conducted with triadimefon applied to an established grape vine and the field trial data conducted with triadimenol applied to the soil of banana groves. The metabolism study conducted with triadimefon applied to grapes indicate that triadimenol is the major metabolite identified at 56% along with KWG 1342 at 16%. The available field trial data indicate that residues of triadimenol and KWG 1342 are both likely to be found in/on bananas as indicated in Table 9.

860.1300 Nature of the Residue - Livestock

The reregistration requirements for livestock metabolism are fulfilled based on acceptable goat and poultry metabolism studies submitted to support reregistration of triadimefon.

For the ruminant study, a lactating goat received [phenyl-14C]triadimefon at 86.4 ppm for three consecutive days in feed. Triadimefon was detected at low levels in milk and fat (<5% TRR) but was not detected in kidney, liver, or muscle. The major residue identified was KWG 1342 glucuronide (6-47% TRR). Triadimenol and its conjugates comprised a major portion of the residue in tissues and milk (totals of 9-42% TRR). The remainder of the radioactivity was identified as KWG 1323 glucuronide (19-22% TRR) and KWG 1342 (1-6% TRR) and its sulfate (1-15% TRR in tissues, 43% TRR in milk).

For the poultry study, 16 laying hens received [phenyl-¹⁴C]triadimefon at 28.7 ppm for three consecutive days in feed. Triadimefon was identified in fat and eggs (4-17% TRR) but was not detected in liver or muscle. Triadimenol and its related compounds were the major metabolites identified (totals of 41-49% TRR). The remainder of the radioactivity was identified as KWG 1342 and its related compounds (totals of 10-36% TRR), p-chlorophenol (liver and fat only at 2-4% TRR), chlorophenoxytriazolyl acetic acid (muscle only at 3% TRR), and KWG 1323 (eggs and fat only at 3-5% TRR).

HED has determined that the residues of concern for tolerance expression and risk assessment in

livestock are triadimenol and KWG 1342. The chemical names and structures of these compounds are presented in Table 3.

860.1340 Residue Analytical Methods - Plants

The Pesticide Analytical Manual (PAM) Vol. II does not contain a listing for triadimenol (February 1997 Index). However, the methods listed for triadimefon can be used for determination of triadimenol, KWG 1342, and KWG 1732. PAM lists two GC/MS methods (Methods I and II) for the determination of triadimenol and its free and conjugated metabolites in all crops. Both methods are common moiety methods. In Method I, residues are extracted using methanol or methanol:acetone (2:1, v:v). Following cleanup on an ion-exchange column, the total residues are hydrolyzed to p-chlorophenol using concentrated HCl. p-Chlorophenol is isolated by steam distillation followed by acid/base partitioning and then derivatized with dinitrofluorobenzene for determination by GC/MS using selected ion monitoring. Residues are expressed in triadimenol equivalents. Method II is similar to Method I. The reported limit of quantitation (LOQ) is 0.05 ppm and limit of detection (LOD) is 0.01 ppm for both methods.

In conjunction with triadimefon reregistration, Bayer has proposed a GC/MS method (Report No. 106549) for enforcement of tolerances for residues of triadimefon, triadimenol, KWG 1342, KWG 1323, and KWG 1732 in/on barley, corn, cotton, oat, rye, and wheat commodities. Briefly, residues are extracted under reflux in methanol:water, hydrolyzed with cellulase at 37°C overnight, and partitioned with dichloromethane:acetonitrile. The aqueous phase, containing KWG 1732, is partitioned with acidic ethyl acetate, and methylated with trimethylsilyl diazomethane for analysis by GC/MS. The dichloromethane phase is cleaned up by gel permeation chromatography and separated by semi-preparative HPLC into two fractions: one containing triadimefon and triadimenol and the other containing KWG 1323 and KWG 1342. Triadimefon and triadimenol are determined directly by GC/MS; KWG 1323 and KWG 1342 are derivatized prior to GC/MS analysis. The method has been successfully radiovalidated and has undergone independent laboratory validation. The reported method LOQ is 0.05 ppm for each analyte in cereal grains and 0.02 ppm in each analyte in cotton.

A GC/NPD method (Report No. 80488) is available for determination of residues of triadimenol, KWG 1342, and KWG 1323 and is adequate for data-collection and tolerance enforcement in bananas. Briefly, residues are extracted under reflux in methanol:water (7:3, v:v) and the extract is buffered and hydrolyzed in cellulase at 37°C overnight to release conjugated residues. Residues are partitioned into dichloromethane, cleaned up by gel permeation chromatography, and separated into parent (triadimenol) and metabolite (KWG 1342) fractions by semi-preparative HPLC. The metabolite fraction residues are derivatized with trifluoroacetic anhydride and all residues are determined using GC/NPD. The method has undergone a successful Agency method validation on tomatoes (PP#4F3148; 4/3/86) and was submitted to the FDA for publication in PAM Vol. II (letter to A. Marcotte from M. Firestone, 4/9/1986), however, the February 1997 update to the PAM Vol. II index does not include an entry for triadimenol. The reported method LOQ is 0.01 ppm for each analyte.

860.1340 Residue Analytical Methods - Livestock

The Pesticide Analytical Manual (PAM) Vol. II does not contain a listing for triadimenol

(February 1997 Index). However, the methods listed for triadimefon can be used for determination of triadimenol and KWG 1342 in livestock commodities. PAM lists two GC/MS methods (Methods I and II) for the determination of triadimenol and its free and conjugated metabolites in livestock commodities; these are the same methods as described above for plant commodities. The reported LOQ is 0.05 and LOD is 0.01 ppm for both methods.

860.1360 Multiresidue Methods

The reregistration requirements for multiresidue method testing for residues of triadimenol and its metabolites are satisfied. The 10/99 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that triadimenol is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method; Protocol D); triadimenol is not recovered using Multiresidue Methods Sections 303 (Mills, Onley, and Gaither; Protocol E, nonfatty) and 304 (Mills, fatty food). Metabolite KWG 1732 is not recovered using Sections 303 and 304. Although multiresidue method testing data have been submitted for KWG 1342, the PESTDATA database does not contain any recovery data for this metabolite.

860.1380 Storage Stability Data - Plants

The reregistration requirements for storage stability data are not satisfied for field corn forage, grain, and stover; sweet corn forage, kernel plus cob with husks removed (K+CWHR), grain, and stover; cotton undelinted seed and gin byproducts; and wheat forage, hay, and straw, and wheat processed commodities pending the results from the requested metabolism studies. Storage stability data for triadimenol, KWG 1342, and KWG 1732 in/on field corn forage, grain, and stover; sweet corn forage, kernel plus cob with husks removed (K+CWHR), grain, and stover; cotton undelinted seed and gin byproducts; and wheat processed commodities are required pending the results from the requested metabolism studies. Storage stability data for KWG 1732 in/on wheat forage, hay, and straw are required pending the results from the requested metabolism studies.

The available storage stability data indicate that residues of triadimenol and its metabolite KWG 1342 are stable for up to 24 months of frozen storage (\le -20°C) in/on the following commodities: apple; cucumber; grapes, grape juice, and raisins; pineapple; sugar beet roots, tops, and molasses; tomatoes; and wheat grain and forage. These analytes are also stable in grape pomace (wet and dry) for up to 6 months. Residues of triadimenol are stable in coffee beans for up to 6 months of frozen storage. When corrected for concurrent method recoveries, residues of triadimenol appear to decline after 24 months in the following crop matrices: asparagus (18%), wheat straw (30%), bran (29%), flour (25%), and grain dust (17%). Residues of KWG 1342 also appeared to decline in asparagus (15%) and wheat bran (20%) after 24 months of frozen storage, and in coffee beans (79%) after 40 days of storage. Additionally, storage stability data indicate that KWG 1732 is stable in wheat grain stored frozen at \le -20°C for up to 2.5 years.

860.1380 Storage Stability Data - Livestock

Adequate storage stability data for residues of triadimenol and KWG 1342 in livestock commodities have been submitted and evaluated in conjunction with triadimefon reregistration. The available storage stability data, collected using samples from the triadimefon livestock

metabolism studies, indicate that residues of triadimefon and its regulated metabolites (including triadimenol, KWG 1323, and KWG 1342) are stable in goat milk, fat, and liver during approximately 14, 26, and 29 months, respectively, of frozen storage. Residues were found to be stable in poultry muscle and eggs during approximately 15 months of frozen storage. These data are adequate to validate the storage intervals of livestock commodity samples collected from the feeding studies.

860.1400 Water, Fish, and Irrigated Crops

Triadimenol is presently not registered for direct use on water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

860.1460 Food Handling

Triadimenol is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

The reregistration requirements for data depicting the magnitude of triadimefon residues of concern in meat, milk, poultry, and eggs have been fulfilled. Acceptable ruminant and poultry feeding studies have been submitted and evaluated (PP#2F2665). In these studies, livestock were fed a 1:1 mixture of triadimefon and triadimenol. Samples were analyzed for bound and free residues of triadimefon, triadimenol, KWG 1342, and KWG 1323 using the GC/MS methods listed in PAM Vol. II. The reported LOQ is 0.05 ppm and LOD is 0.01 ppm for both methods. The theoretical dietary burden (TDB) to livestock is presented below in Table 6.

Table 6. Calculation of Dietary Burdens of Triadimenol to Livestock.							
Feed Commodity	% Dry Matter ¹	% Diet ¹ Tolerance (ppm) ²		Dietary Contribution (ppm) ³			
		Beef Cattle					
Corn, field, forage	40	20	0.05	0.025			
Corn, field, grain	88	40	0.05	0.023			
Corn, field, stover	83	25	0.05	0.015			
Cotton, undelinted seed, meal	89	15	0.02	0.003			
TOTAL BURDEN	N/A ⁴	100	N/A	0.066			
		Dairy Cattle					
Corn, field, forage	40	35	0.05	0.044			
Corn, field, grain	88	35	0.05	0.020			
Corn, field, stover	83	15	0.05	0.009			
Cotton, undelinted seed, meal	89	15	0.02	0.003			
TOTAL BURDEN	N/A	100	N/A	0.076			
	Poultry and Swine						
Corn, field, grain	N/A	85	0.05	0.043			
Cotton, undelinted seed, meal	N/A	15	0.02	0.003			

Triadimenol	Summary Analytical Chemistry and Residue Data - TRED	DP Barcode: 314891
Table 6. Calculat	tion of Dietary Burdens of Triadimenol to Livestock.	

0.046

N/A

- 1. OPPTS Guideline 860.1200, Table 1 (August 1996).
- 2. Reassessed tolerances from Table 14.
- 3. Contribution = $(\% \text{ diet } / \% \text{ dry matter}) \times (\text{reassessed tolerance}).$

N/A

4. N/A = Not applicable.

TOTAL BURDEN

Ruminant. In the ruminant feeding study, cattle were fed triadimenol:triadimefon (1:1) at total dose levels of 25, 75, and 250 ppm. The resulting triadimenol dose levels of 12.5, 37.5, and 125 ppm represent 189x, 568x, and 1890x the theoretical dietary burden to beef cattle, and 164x, 493x, and 1650x the TDB to dairy cattle. The results of the study are summarized in Table 7.

	Table 7. Estimation of Potential Triadimefon, Triadimenol, KWG 1342, and KWG 1323 Residues in Milk and Tissues of Beef and Dairy Cows Using Data from the Ruminant Feeding Study.									
Matrix	25 ppm feeding level (12.5 ppm triadimenol) ¹	Estimated residues at 1x TDB using 25 ppm feeding level ²	75 ppm feeding level (37.5 ppm triadimenol) ¹	Estimated residues at 1x TDB using 75 ppm feeding level ²	250 ppm feeding level (125 ppm triadimenol) ¹	Estimated residues at 1x TDB using 250 ppm feeding level ²				
Milk	0.014 (0.007)	0.000043	0.035 (0.018)	0.000036	0.076 (0.038)	0.000023				
Muscle	< 0.01	0.000026	0.019 (0.009)	0.000016	0.043 (0.022)	0.000012				
Kidney	0.412 (0.206)	0.0011	0.787 (0.394)	0.00069	2.27 (1.14)	0.00060				
Liver	0.093 (0.047)	0.00025	0.287 (0.144)	0.00025	1.00 (0.50)	0.00026				
Fat	0.024 (0.012)	0.000063	0.086 (0.043)	0.000076	0.211 (0.106)	0.000056				

^{1.} Numbers in parentheses refer to triadimenol residue levels and were used to calculate the estimated residues at 1x TDB. It is assumed that one-half of the total residues found is due to triadimenol.

The maximum residue of triadimenol observed in any matrix in the ruminant feeding study was kidney at 0.206 ppm after dosing at an exaggerated feeding level of 12.5 ppm or 189x the beef cattle dietary burden. Based on the 189x dosing level for beef cattle, the maximum expected residues of triadimenol in kidney at a 10x level are 0.011 ppm, which is less than the livestock method LOQ of 0.05 ppm.

Swine. A swine feeding study is not available; therefore, maximum potential residues resulting from dietary exposure were estimated using data from the above ruminant feeding study. The maximum residue of triadimenol observed in any matrix in the ruminant feeding study was kidney at 0.206 ppm after dosing at an exaggerated feeding level of 12.5 ppm or 272x the swine theoretical dietary burden. Based on the 272x dosing level for swine, the maximum expected residues of triadimenol in kidney at a 10x level are 0.0076 ppm, which is less than the livestock method LOQ of 0.05 ppm.

Poultry. In the poultry feeding study, laying hens were fed triadimenol:triadimefon (1:1) at dose levels of 10, 25, 75, and 250 ppm for 29 days. The resulting triadimenol dose levels of 5, 12.5, 37.5, and 125 ppm represent 109x, 272x, 815x, and 2720x the theoretical dietary burden to poultry. Egg samples were collected daily on days 24 through 28 of the study. All tissue samples

^{2.} Estimated triadimenol residues = (total dietary contribution, Table 6 / feeding level) x (residue from feeding studies; residues reported at less than the LOD of 0.01, half the LOD was used). Whole milk was calculated using TDB from dairy cattle. Muscle, fat, liver, and kidney were calculated using TDB from beef cattle.

from the highest dosing level were analyzed; only liver, which was found to contain the maximum residues, was analyzed at lower dosing levels. The results of the study are summarized in Table 8.

		of Potential Tr Hens Using I		,	,	/	G 1323 Res	idues in Eggs
Matrix	10 ppm feeding level (5 ppm)	Estimated residues at 1x TDB using 10 ppm feeding level ¹	25 ppm feeding level (12.5 ppm)	Estimated residues at 1x TDB using 25 ppm feeding level ¹	75 ppm feeding level (37.5 ppm)	Estimated residues at 1x TDB using 75 ppm feeding level ¹	250 ppm feeding level (125 ppm)	Estimated residues at 1x TDB using 250 ppm feeding level ¹
Muscle	ND ³	N/A ³	ND	N/A	ND	N/A	0.023 (0.016)	0.0000058
Fat	ND	N/A	ND	N/A	ND	N/A	0.148 (0.074)	0.000027
Skin	ND	N/A	ND	N/A	ND	N/A	0.199 (0.099)	0.000036
Gizzard	ND	N/A	ND	N/A	ND	N/A	0.090 (0.045)	0.000017
Liver	0.045 (0.023)	0.00021	0.085 (0.043)	0.00016	0.288 (0.144)	0.00018	1.406 (0.703)	0.00026
Eggs	0.031 (0.016)	0.00015	0.071 (0.036)	0.00013	0.225 (0.133)	0.00016	1.188 (0.594	0.00022

- 1. Numbers in parentheses refer to triadimenol residue levels and were used to calculate the estimated residues at 1x TDB. It is assumed that one-half of the total residues found is due to triadimenol.
- 2. Estimated triadimenol residues = (total dietary contribution, Table 6 / feeding level) x (residue from feeding studies; residues reported at less than the LOD of 0.01, half the LOD was used).
- 3. ND = Not determined; N/A = Not applicable.

The maximum residue of triadimenol observed in any matrix in the poultry feeding study was liver at 0.703 ppm after dosing at an exaggerated feeding level of 125 ppm or 2720x the poultry dietary burden. Based on the 2720x dosing level for poultry, the maximum expected residues of triadimenol in liver at a 1x level are 0.00026 ppm, which is less than the livestock method LOQ of 0.05 ppm.

Triadimenol is not registered for use as a direct livestock treatment. The nature of the residue in livestock is adequately defined for the current uses. HED concludes that the supported registered uses on barley, corn, cotton, oats, rye, and wheat result in a 40 CFR §180.6(a)(3) situation for ruminant commodities; i.e., there is no reasonable expectation of finite residues in ruminant commodities. Therefore, additional data on the transfer of residues to meat, milk, poultry, and eggs are not required and all tolerances for livestock commodities should be revoked pending results from the requested corn and wheat metabolism studies. If registration on additional commodities and livestock feed items are requested, then triazole and phenyl-labeled livestock metabolism studies would be required. Such data may, in turn, trigger the need for magnitude of the residue (feeding) studies in livestock.

860.1500 Crop Field Trials

The reregistration requirements for magnitude of the residue in/on bananas are fulfilled. Additional field trials conducted with field corn (forage, grain, stover), sweet corn (forage, K+CWHR, grain, and stover), cotton (undelinted seed and gin byproducts), and wheat (forage, grain, hay, and straw) are required pending the results from the requested metabolism studies.

Currently, triadimenol is registered for use on barley, corn, cotton, oats, rye, sorghum, and wheat. No data are available to support use of triadimenol on sorghum, however, Bayer has indicated that it no longer intends to support this use. Additionally, an import tolerance on bananas has been established. Use of triadimenol on bananas to be imported into the U.S. is supported by Bayer. At the time of the tolerance petition, Bayer indicated that it intended to register triadimenol products for use on bananas in Costa Rice, Guatemala, Honduras, and Equador.

Details of any required label amendments are presented in the endnotes for 860.1200 Directions for Use and respective crop sections for 860.1500 Crop Field Trials of Table 5. Refer to Tolerance Reassessment Summary section for recommendations with respect to established tolerance levels. Final determination of the adequacy of the submitted field trial data for barley, corn, cotton, oats, rye, and wheat will be withheld until the confirmatory metabolism data is submitted.

As a result of changes to Table 1 of OPPTS 860.1000, crop field trial data are now required for the following RACs which have been added to Table 1: barley hay, cotton gin byproducts, oat hay, and wheat hay. Additionally, field trials conducted with wheat are required pending the results from the requested metabolism studies. The required field trial data for wheat may be translated to barley, rye, and oats.

Data pertaining to triadimenol residues of concern in/on aspirated grain fractions are not required because triadimenol is applied as a seed treatment.

Banana (MRID 40615201)

Data submitted reflect eleven field trials from Costa Rica and Honduras in which soil application of banana groves were made once to three times using 0.75 to 2.0 gm ai/pu (production unit; 640-800 production units grown per acre) of triadimenol 1% or 3% G. The use rate of 0.75 gm ai/pu would result in a rate of 1.06 to 1.32 lb ai/A. Banana samples were collected and frozen for a maximum of 180 days prior to analysis for residues of triadimenol and KWG 1342 using the GC/NPD method (Report No. 80488). Pre-harvest intervals (PHIs) ranged from 0 to 203 days. No storage stability data was submitted as data for wheat grain, wheat forage, apples and grapes showed no significant loss of residues after two years. The calculated maximum residue in whole fruit (pulp and peel) was reported at 0.14 ppm. The sample reflects one application using 1 gm ai/pu with a 203-day PHI. Measurable residues of triadimenol and KWG 1342 were reported in the pulp and peel on day of application and at all reported PHIs ranging up to 203 days. The bulk of residues concentrate in peel, almost 2 to 8 times that in pulp, depending on dosage and/or number of applications. Residues in the pulp did not exceed 0.075 ppm at all dosages and PHIs tested (up to 2.7x rate and 203-day PHI). At the 1x rate of 0.75 gm ai/pu, total residues in whole bananas did not exceed 0.10 ppm, reflecting 130-day PHI. The next highest level was 0.09 ppm reflecting a 43-day PHI. At higher rates, two residue values were noted, 0.17 ppm reflecting a 2x rate, with a 130-day PHI; and 0.14 ppm reflecting a 1.3x rate, with a 203-day PHI. The results are summarized below in Table 9.

Table 9. B	anana Fie	eld Trial l	Residue Data.						
Applic. No of PHI Residues (ppm)									
rate in gm ai/pu	applic.	(days)		Pulp Peel				Whole Fruit ²	
			Triadimenol	KWG 1342	Total	Triadimenol	KWG 1342	Total	Total
1.0 (1.3x)	1	63	ND	ND	0.015	0.01	0.03	0.04	0.02
1.0 (1.3x)	1	79	ND	ND	0.015	0.02	0.03	0.05	0.03
1.0 (1.3x)	1	91	0.02	ND	0.03	0.01	0.03	0.04	0.03

^{1.} ND = Not detected or less than LOD. One-half the LOD value was used; 0.005 ppm for triadimenol and 0.01 ppm for KWG 1342, for calculating total.

These data indicate that the combined residues of triadimenol and KWG 1342 are not likely to exceed the established tolerance of 0.2 ppm in/on bananas following application at the maximum registered rate of 0.75 gm ai/pu with a 0-day PHI.

Corn (MRIDs 00125407-00125409)

Samples were obtained from crops grown in MD, MN, NE, TX, FL, IL, MS, IN, KS, GA, OR, and Canada. The geographical representation is considered adequate for reregistration. The crops were grown from seed treated with triadimenol at a rate of 1 oz ai/100 lbs of seed. The samples were analyzed for triadimenol and KWG 1342. The residues in various components were as follows: green forage, <0.01-0.02 ppm (LOD = 0.01) with PHIs of 31-146 days; dry forage, <0.01 ppm with PHIs of 88-159 days; dry kernels, <0.01 ppm with PHIs of 88-159 days; dry husks, <0.01 ppm with PHIs of 88-159 days; milk-stage kernels, <0.01 ppm with PHIs of 63-146 days; milk-stage cob, <0.01 ppm with PHIs of 63-146 days; K+CWHR, <0.01 ppm with PHIs of 63-146 days.

The data show that residues, if present, in grain, forage, or fodder of field corn, popcorn, and sweet corn are not likely to exceed the established tolerances of 0.05 ppm following application at the maximum registered rate of 1 oz ai/100 lbs of seed.

Cotton (MRID 41242801)

Nine crop field trials were conducted on cotton seed and forage in five states (AZ, one site; CA, 4 sites; MS, two sites; OK, one site; TX, one site). The geographical representation is considered adequate for reregistration. All studies involved a single seed treatment with triadimenol (30% FIC) at a rate of 3 oz formulation/100 lbs of seed (1 oz ai/100 lbs of seed). At all locations, treated seeds were received at each site from Gustafon International Research Laboratory in TX and stored at room temperature under cool, dry conditions until planting. At maturity, the raw agricultural commodities cotton seed and cotton forage were randomly harvested by hand and samples were shipped frozen to Morse Laboratories in Sacramento, CA. Upon receipt, samples were stored in a freezer at ≤-18°C until removed for sample preparation (2-10 weeks). No storage stability data was submitted as data for wheat grain, wheat forage, apples and grapes

^{2.} Total whole fruit was calculated based on a 2:1 ratio of pulp to peel ([total pulp residue in ppm * 2/3] + [total peel residue in ppm * 1/3]).

showed no significant loss of residues after two years. The samples were analyzed for triadimenol and KWG 1342 using a GC/NPD data-collection method developed by Mobay Chemical Corporation. The reported LOD in this study is 0.01 ppm in cotton seed and forage. The recoveries reported for fortified samples of cotton seed (0.02 ppm) and cotton forage (0.5 ppm) ranged from 72 to 118%. A total of 35 samples were analyzed for triadimenol and KWG 1342, and no detectable residues were found in either cotton seed or forage at harvest.

These data indicate that the combined residues of triadimenol and KWG 1342 are not likely to exceed the established tolerance of 0.02 ppm in/on cotton seed following application at the maximum registered rate of 1 oz ai/100 lbs of seed. The established tolerance for cotton forage should be revoked since it is no longer considered a significant livestock feed item. Additionally, field trial data for cotton gin byproducts are required.

Wheat (MRID 42712101)

Seven crop field trials were conducted on spring (5) and winter (2) seeded wheat in seven states (MN, CA, ID, ND, WA, IN, KS). The geographical representation is considered adequate for reregistration. All studies involved a single seed treatment with triadimenol (Baytan® 2.6 FS Seed Treatment Fungicide) at a rate of 0.5 oz ai/100 lbs of seed. Earliest grazing forage and earliest harvest grain and straw samples were collected and analyzed for residues of triadimenol and KWG 1342 using the GC/NPD method (Report No. 80488). Pre-harvest intervals (PHIs) ranged from 33 to 196 days for forage and 83-296 days for grain and straw. Samples were frozen following collection and shipped to Miles Inc. for processing. Forage, hay and straw samples were chopped in the presence of dry ice, and grain samples were milled while frozen. Samples were subsequently frozen and transported to ABC Laboratories, Inc., Columbia, Missouri. All samples were stored frozen prior to analysis. The results are summarized below in Table 10.

Table 10. V	Vheat Field Trial Residue D	Pata. ¹			Table 10. Wheat Field Trial Residue Data. ¹							
Matrix	Location/Field Trial ID	Variety	PHI (days) ²	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ³						
	MN/251-BT001-89H	Spring	41	< 0.01	< 0.01	0.01						
	ND/251-BT002-89H	Spring	33	0.03	< 0.01	0.035						
	ID/452-BT004-89H	Spring	44	< 0.01	< 0.01	0.01						
Forage	WA/454-BT006-89H	Spring	47	0.03	< 0.01	0.035						
	CA/457-BT007-89H	Spring	45	0.17	< 0.01	0.18						
	IN/HIN-BT008-89H	Winter	196	0.03	< 0.01	0.035						
	KS/STF-BT009-89H	Winter	68	0.03	< 0.01	0.035						
	MN/251-BT001-89H	Spring	83	< 0.01	< 0.01	0.01						
	ND/251-BT002-89H	Spring	90	< 0.01	< 0.01	0.01						
Grain	ID/452-BT004-89H	Spring	127	< 0.01	< 0.01	0.01						
	WA/454-BT006-89H	Spring	108	< 0.01	< 0.01	0.01						
	IN/HIN-BT008-89H	Winter	296	< 0.01	< 0.01	0.01						

Table 10. Wheat Field Trial Residue Data. ¹							
Matrix	Location/Field Trial ID	Variety	PHI (days) ²	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ³	
	KS/STF-BT009-89H	Winter	286	< 0.01	0.02	0.025	
	MN/251-BT001-89H	Spring	83	0.11	0.04	0.15	
	ND/251-BT002-89H	Spring	90	< 0.01	< 0.01	0.01	
G.	ID/452-BT004-89H	Spring	127	0.01	< 0.01	0.01	
Straw	WA/454-BT006-89H	Spring	108	< 0.01	< 0.01	0.01	
	IN/HIN-BT008-89H	Winter	296	0.02	< 0.01	0.025	
	KS/STF-BT009-89H	Winter	286	< 0.01	< 0.01	0.01	

- 1. Result of a single seed treatment application at approximately 0.5 oz ai/100 lbs of seed.
- 2. Forage samples were collected at earliest grazing. Grain and straw samples were collected at earliest harvest.
- 3. Residues with reported value of <0.01 (LOQ = 0.01) are assigned a value of one-half the LOQ for the purpose of calculating the total residue.

These data indicate that the combined residues of triadimenol and KWG 1342 are not likely to exceed the established tolerances of 0.05 ppm in/on wheat grain and 0.2 ppm in/on wheat straw following application at the maximum registered rate of 0.5 oz ai/100 lbs of seed, however, the established tolerance for wheat forage is too high and should be reduced to 0.5 ppm.

Barley (MRID 42696308)

Six barley field trials were conducted in CA, MN, KS, ID, ND and WA to collect residue data as a result of a single seed treatment application of triadimenol (Baytan® 2.6 FS Seed Treatment Fungicide) at a rate of 0.5 oz ai/100 lbs of seed. The geographical representation is considered adequate for reregistration. Earliest grazing forage and earliest harvest grain and straw samples were collected and analyzed for residues of triadimenol and KWG 1342 using the GC/NPD method (Report No. 80488). PHIs ranged from 33 to 68 days for forage and 83-282 days for grain and straw. Samples were transported to Miles Inc. for processing. Forage and straw samples were chopped in the presence of dry ice, and grain samples were milled while frozen. Samples were shipped frozen to ABC Laboratories, Inc., Columbia, Missouri and stored frozen prior to analysis. The analytical results reported are summarized below in Table 11.

Table 11. Barley Field Trial Residue Data. ¹							
Matrix	Location/Field Trial ID	Variety	PHI (days) ²	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ³	
	MN/251-BT010-89H	Spring	41	0.02	< 0.01	0.025	
	ND/251-BT011-89H	Spring	33	0.02	< 0.01	0.025	
	ID/452-BT012-89H	Spring	44	0.03	< 0.01	0.035	
Forage	WA/454-BT014-89H	Spring	47	0.03	< 0.01	0.035	
	CA/457-BT015-89H	Spring	45	0.07	< 0.01	0.075	
	KS/STF-BT016-89H	Winter	68	0.03	< 0.01	0.035	

Table 11. Barley Field Trial Residue Data. ¹							
Matrix	Location/Field Trial ID	Variety	PHI (days) ²	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ³	
	MN/251-BT010-89H	Spring	83	0.02	< 0.01	0.025	
	ND/251-BT011-89H	Spring	87	< 0.01	< 0.01	0.01	
Grain	ID/452-BT012-89H	Spring	110	< 0.01	< 0.01	0.01	
	WA/454-BT014-89H	Spring	108	< 0.01	< 0.01	0.01	
	KS/STF-BT016-89H	Winter	282	< 0.01	< 0.01	0.01	
	MN/251-BT010-89H	Spring	83	0.05 0.05	<0.01 <0.01	0.055 0.055	
	ND/251-BT011-89H	Spring	87	< 0.01	< 0.01	0.01	
Straw	ID/452-BT012-89H	Spring	110	< 0.01	0.01	0.015	
	WA/454-BT014-89H	Spring	108	0.01	< 0.01	0.015	
	KS/STF-BT016-89H	Winter	282	< 0.01	< 0.01	0.01	

- 1. Result of a single seed treatment application at approximately 0.5 oz ai/100 lbs of seed.
- 2. Forage samples were collected at earliest grazing. Grain and straw samples were collected at earliest harvest.
- 3. Residues with reported value of <0.01 (LOQ = 0.01) are assigned a value of one-half the LOQ for the purpose of calculating the total residue.

These data indicate that the combined residues of triadimenol and KWG 1342 are not likely to exceed the established tolerances of 0.05 ppm in/on barley grain and 0.2 ppm in/on barley straw following application at the maximum registered rate of 0.5 oz ai/100 lbs of seed.

Oats (MRID 42696309)

Six crop field trials were conducted in IA, MN, KS, NY, IN and WI on oats. The geographical representation is considered adequate for reregistration. Each study involved a single seed treatment with triadimenol (Baytan® 2.6 FS Seed Treatment Fungicide) at a rate of 0.5 oz ai/100 lbs of seed. Earliest grazing forage and earliest harvest grain and straw samples were collected and analyzed for residues of triadimenol and KWG 1342 using the GC/NPD method (Report No. 80488). PHIs ranged from 35 to 73 days for forage and 83-122 days for grain and straw. Samples were frozen following collection and shipped to Miles Inc. for processing. Forage, hay and straw samples were chopped in the presence of dry ice, and grain samples were milled while frozen. Samples were subsequently frozen and transported to ABC Laboratories, Inc., Columbia, Missouri. All samples were stored frozen prior to analysis. The results are summarized below in Table 12.

Table 12. Oat Field Trial Residue Data. ¹						
Matrix	Location/Field Trial ID	PHI (days) ²	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ³	
T.	MN/251-BT-017-89H	41	0.01	< 0.01	0.015	
Forage	IA/255-BT018-89H	39	0.07	< 0.01	0.075	

Table 12. Oat Field Trial Residue Data. ¹							
Matrix	Location/Field Trial ID	PHI (days) ²	Triadimenol (ppm)	KWG 1342 (ppm)	Total (ppm) ³		
	NY/758-BT019-89H	35	0.26	< 0.01	0.27		
	WI/851-BT020-89H	42	0.09	< 0.01	0.095		
	IN/HIN-BT021-89H	53	0.14	< 0.01	0.15		
	KS/STF-BT022-89H	73	< 0.01	< 0.01	0.01		
	MN/251-BT-017-89H	83	< 0.01	< 0.01	0.01		
	IA/255-BT018-89H	92	< 0.01	< 0.01	0.01		
a .	NY/758-BT019-89H	114	<0.01	< 0.01	0.01		
Grain	WI/851-BT020-89H	98	< 0.01	< 0.01	0.01		
	IN/HIN-BT021-89H	107	< 0.01	< 0.01	0.01		
	KS/STF-BT022-89H	122	< 0.01	<0.01	0.01		
	MN/251-BT-017-89H	83	0.02	< 0.01	0.025		
	IA/255-BT018-89H	92	<0.01	<0.01	0.01		
	NY/758-BT019-89H	114	< 0.01	<0.01	0.01		
Straw	WI/851-BT020-89H	98	0.03	0.02	0.05		
	IN/HIN-BT021-89H	107	< 0.01	<0.01	0.01		
	KS/STF-BT022-89H	122	< 0.01	0.02	0.025		

- 1. Result of a single seed treatment application at approximately 0.5 oz ai/100 lbs of seed.
- 2. Forage samples were collected at earliest grazing. Grain and straw samples were collected at earliest harvest.
- 3. Residues with reported value of <0.01 (LOQ = 0.01) are assigned a value of one-half the LOQ for the purpose of calculating the total residue.

These data indicate that the combined residues of triadimenol and KWG 1342 are not likely to exceed the established tolerances of 0.05 ppm in/on oat grain and 0.2 ppm in/on oat straw following application at the maximum registered rate of 0.5 oz ai/100 lbs of seed, however, the established tolerance for oat forage is too high and should be reduced to 0.5 ppm.

860.1520 Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed commodities of field corn and cotton have been fulfilled. Crop field trial data for field corn (MRID 44519801) and cotton (MRID 44519802) indicate that residues of triadimenol, KWG 1342, and KWG 1732 were nonquantifiable using the GC/MS method (Report No. 106549) following treatment at 5x the maximum application rate of 1 oz ai/100 lbs of seed; therefore, processing studies for these commodities were not conducted.

The registrant submitted a wheat processing study (MRID 44519803) depicting the potential for concentration of triadimenol residues of concern in wheat processed commodities and was found to be inadequate. Wheat seed was treated with the 2.65 lb/gal FIC formulation at 2.5 oz ai/100

lbs of seed (5x the maximum application rate) prior to planting. The treated seed was planted in TX 18 days after treatment. The registrant noted that the treated seed did not grow as well as the untreated seed, and that the treated plot suffered 40-50% loss due to winter freezing conditions. One sample of wheat grain grown from untreated seed and two samples of wheat grain grown from treated seed were collected at maturity, 308 days after planting. The wheat grain samples were placed in frozen storage within 4 hours of collection, and then shipped frozen to the analytical laboratory (ABC Laboratories, Inc.), where they were stored frozen until analysis.

Wheat grain samples were analyzed for residues of triadimenol, KWG 1342, and KWG 1732 using the GC/MS method (Report No. 106549). Residues were below the LOQ (<0.05 ppm) for each analyte in/on one sample of untreated wheat grain. Residues of triadimenol and KWG 1342 were below the LOQ in/on two samples of treated wheat grain. Detectable residues of KWG 1732 were observed in the wheat grain samples at 0.11 and 0.23 ppm.

The registrant did not process seed from the above 5x field trial; instead, cited a wheat processing study submitted to fulfill reregistration requirements for triadimefon (MRID 44029301). In that study, mature wheat grain was harvested 35 days following the last of two foliar broadcast applications of a 50% WP triadimefon formulation at 0.9 lb ai/A/application (ca. 4x the maximum seasonal use rate for triadimefon). At the processing facility (Texas A&M University Food Protein and Development Center, Bryan, TX), aspirated grain fractions were collected (data for aspirated grain fractions are not presented here) and wheat grain samples were processed into bran, wheat germ, flour, middlings, and shorts, using a small-scale processing procedure which simulated normal commercial processing conditions. These data indicate that the combined residues of triadimenol, KWG 1342, and KWG 1732 concentrate by 2.1x in wheat bran but do not concentrate in wheat flour, middlings, shorts, or germ.

The available wheat grain data do not fulfill the requirement for a wheat grain processing study. Residues of triadimenol and KWG 1342 were each <LOQ (<0.05 ppm) and residues of KWG 1732 were 0.11 and 0.23 ppm in/on two samples of wheat grain grown from seed treated with triadimenol (FIC) at 5x the maximum rate. However, the treated grain was not processed. Instead, the registrant proposed translating data from a triadimenon wheat grain processing study; however, these data cannot be translated to triadimenol due to differences in the use patterns (seed treatment vs. late season foliar sprays) that are likely to impact the potential concentration of residues. A wheat processing study conducted with triadimenol applied to wheat as a seed treatment should be submitted once the requested wheat metabolism studies have been submitted and reviewed.

860.1650 Submittal of Analytical Reference Standards

An analytical reference standard for triadimenol was submitted by Bayer CropScience in November of 2001 and expires November of 2013. The standard is available at the EPA National Pesticide Standards Repository.

860.1850 Confined Accumulation in Rotational Crops and 860.1900 Field Accumulation in Rotational Crops

The reregistration requirements for accumulation in rotational crops are fulfilled, pending results

from the requested wheat and corn triazole labeled metabolism studies. With the available data, HED concludes that the metabolism of triadimenol in rotational crops (root crop, leafy vegetable, and grain crop) is consistent with the metabolism investigated in the primary crop, wheat. Final determination of the metabolites of concern will be withheld until the requested metabolism studies have been submitted and reviewed. No data pertaining to confined/field accumulation of triadimenol residues in rotational crops have been submitted. Confined rotational crop data for triadimefon have been submitted by Bayer (S. Knizner, D186937, MRID 42613301, 11/3/93). The study successfully characterized and identified ≥87% of the total ¹⁴C-residues in/on all crop commodities. Total ¹⁴C-residues exceeded 0.01 ppm in/on the commodities of wheat, lettuce, and radish that were planted 29, 161, and 270 days after [phenyl-14C]triadimefon was applied at 5.8 lb ai/A. The uptake of residues was lowest in radish bulbs (0.30 ppm) and highest in wheat straw/chaff (38.46 ppm). The pattern of accumulation in relation to rotation intervals could not readily be established in radish commodities; accumulation was highest at the 29-day rotation and declined in subsequent intervals, but in lettuce and wheat commodities, accumulation was lowest at the 29-day rotation and increased thereafter. Triadimefon was identified and quantified as a minor residue (≤4% of TRR) in/on the organosoluble fractions of all commodities, except in wheat grain where the parent was below the limit of detection (0.0072 ppm). The principal metabolites identified in leafy commodities and radish bulbs were triadimenol and its acetylated or glucoside derivatives; collectively, these metabolites accounted for 93% of TRR in 29-DAT lettuce, 67% of TRR in 161-DAT wheat straw and 270-DAT immature wheat or wheat forage, and 87% of TRR in radish bulbs. In wheat grain, the predominant compound identified was KWG 1732 which comprised 63-91% of TRR.

Based on this study, the Agency required limited field rotational crop studies for triadimefon. Subsequently, Bayer requested deletion of all rotatable crop uses from its triadimefon product labels.

The available confined rotational crop data for triadimefon indicate a potential for accumulation of triadimenol residues of concern in/on rotatable crops. However, the application rate used in the study is much greater than the expected "application" rate resulting from application of triadimenol to seed. In recently submitted triadimenol processing studies (MRID 44519801-44519803), treated seed was planted at the rate of 13 lb of seed/acre (field corn), 16 lb/acre (cotton), and 91 lb/acre (wheat). Based on maximum application rates of 0.062 lb ai per 100 lb of seed for corn and cotton and 0.031 lb per 100 lb of seed for wheat, the equivalent "soil application" rates would be approximately 0.01 lb ai/A for corn and cotton, and 0.03 lb ai/A for wheat. Therefore, the application rate of the triadimefon rotational crop study is approximately 190x the maximum triadimenol rate for annual crops. If the highest residue found in rotational crops, 19.0 ppm triadimenol in wheat straw, is "corrected" down to a 1x application, expected residues would be 0.1 ppm, which is greater than 0.01 ppm. Therefore, the Agency concludes that limited field rotational crop studies for triadimenol must be submitted pending the results from the requested metabolism studies.

Tolerance Reassessment Summary

Tolerances for residues in/on plant and livestock commodities are established under 40 CFR \$180.450. Tolerances for plant commodities are established under 40 CFR \$180.450 (a) and are currently expressed in terms of the combined residues of triadimenol [β -(4-chlorophenoxy)- α -

(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol] and its butanediol metabolite [4-(4-chlorophenoxy)-2,2-dimethyl-4-(1H-1,2,4-triazol-1-yl)-1,3-butanediol], calculated as triadimenol. Tolerances for livestock commodities are established under 40 CFR §180.450 (b) and are currently expressed in terms of the combined residues triadimenol and its metabolites containing the chlorophenoxy moiety, calculated as triadimenol.

The listing of triadimenol tolerances under 40 CFR §180.450 should be subdivided into parts (a), (b), (c), and (d). Part (a) should be reserved for commodities with permanent tolerances, part (b) for Section 18 emergency exemptions, part (c) for tolerances with regional registrations, and part (d) for indirect or inadvertent residues. In addition, the tolerance expression for plant commodities should be revised to state that combined residues are "expressed as triadimenol" and not "calculated as triadimenol." The reorganization of triadimenol tolerances should be conducted as depicted below in Table 13.

Table 13. Reorg	Table 13. Reorganization of Triadimefon Tolerances Required Under 40 CFR.				
40 CFR	Section Reserved For	Tolerance Expression			
§180.450(a)(1)	barley, corn, cotton, oats, rye, and wheat	Tolerances are established for the combined residues of the fungicide β -(4-chlorophenoxy)- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol [triadimenol], 1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol [KWG 1342], and 1-(4-chlorophenoxy)-1-(1H-1,2,4-triazol-1-yl)ethanoic acid [KWG 1732], expressed as triadimenol, in or on the following raw agricultural commodities:			
§180.450(a)(2)	banana	Tolerances are established for the combined residues of the fungicide β -(4-chlorophenoxy)- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol [triadimenol] and 1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol [KWG 1342], expressed as triadimenol, in or on the following raw agricultural commodities:			

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS 860.1000). As a result of changes to Table 1, tolerances are now required for RACs which have been added to Table 1. Also, some commodity definitions must be corrected. A summary of triadimenol tolerance reassessments is presented in Table 14.

Tolerances Established Under 40 CFR §180.450(a)

Sufficient field trial data reflecting the maximum label use pattern are available to reassess the established tolerance for bananas.

Insufficient data are available to ascertain the adequacy of the established tolerances for the following: field corn (forage, grain, stover), sweet corn (forage, K+CWHR, grain, and stover), cotton (undelinted seed and gin byproducts), and wheat (forage, grain, hay, and straw). Final data requirements for these commodities will be withheld until the required corn and wheat metabolism studies are submitted and reviewed. The required field trial data for wheat may be translated to barley, rye, and oats.

The established tolerance for cotton forage should be revoked because this commodity is no longer considered a significant livestock feed item.

Tolerances To Be Proposed Under 40 CFR §180.450(a)

Because of changes to Table 1 (OPPTS 860.1000), tolerances for barley hay, cotton gin byproducts, oat hay, and wheat hay must be proposed. There are no data available for wheat hay reflecting application according to the currently registered use pattern. The required data for wheat hay will be translated to barley and oat hay.

Tolerances Established Under 40 CFR §180.450(b)

Acceptable feeding studies for ruminants and poultry are available to reassess the tolerances for the livestock commodities.

Triadimenol is not registered for use as a direct livestock treatment. The nature of the residue in livestock is adequately defined for the current uses. HED concludes that the supported uses on barley, corn, cotton, oats, rye, and wheat result in a 40 CFR §180.6(a)(3) situation for ruminant commodities; i.e., there is no reasonable expectation of finite residues in ruminant commodities. Therefore, additional data on the transfer of residues to meat, milk, poultry, and eggs are not required and all tolerances for livestock commodities should be revoked.

Table 14. Tolerance Reassessment Summary for Triadimenol.						
Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]			
	Tolerances Establ	ished Under 40 CFR	§180.450 (a)			
Banana (whole) ¹	0.2	0.2				
Barley, grain	0.05	TBD^2				
Barley, straw	0.2	TBD				
Corn, forage	0.05	TBD	[Corn, field, forage] [Corn, sweet, forage]			
Corn, fresh (including sweet), (K+CWHR)	0.05	TBD	[Corn, sweet, K+CWHR]			
Corn, grain	0.05	TBD	[Corn, field, grain] [Corn, pop, grain]			
Corn, stover	0.05	TBD	[Corn, field, stover] [Corn, pop, stover] [Corn, sweet, stover]			
Cotton, forage	0.02	Revoke	No longer considered a significant livestock feed item.			
Cotton, undelinted seed	0.02	TBD				
Oat, forage	2.5	TBD				

tolerance for milk is not required.

Table 14. Tolerance Rea	Table 14. Tolerance Reassessment Summary for Triadimenol.							
Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]					
Poultry, fat	0.01							
Poultry, meat	0.01	Revoke	The available data indicate that tolerances for poultry commodities are					
Poultry, meat byproducts	0.01	revoke	not required.					
Sheep, fat	0.1		The available data indicate that					
Sheep, meat	0.1	Revoke	tolerances for sheep commodities are					
Sheep, meat byproducts	0.1		not required.					
	Tolerances To Be Pr	roposed Under 40 CFI	R §180.450 (a)					
Barley, hay	None established	TBD						
Cotton, gin byproducts	None established	TBD						
Oat, hay	None established	TBD						
Wheat, hay	None established	TBD						

^{1. 40} CFR §180.450(a) states that there are no U.S. registrations for banana (whole) as of 9/22/93.

Codex Harmonization

The Codex Alimentarius Commission (Codex) has established several maximum residue limits (MRLs) for triadimenol in/on various raw agricultural commodities. The Codex MRLs are expressed in terms of triadimenol *per se*. The MRLs have been established to accommodate triadimenol residues resulting from the use of triadimefon and/or triadimenol. Compatibility cannot be achieved with the Codex MRLs because these levels are expressed in terms of triadimenol only; the U.S. tolerances for plant commodities are expressed in terms of triadimenol, KWG 1342, and KWG 1732 in/on cereal grains and cotton and triadimenol and KWG 1342 in/on bananas. Additionally, all U.S. livestock tolerances should be revoked. A numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 15.

Table 15. Codex MRLs for Triadimenol and Applicable U.S. Tolerances.						
Codex			Reassessed			
Commodity (As Defined)	MRL ¹ (mg/kg)	Step	U.S. Tolerance (ppm)	CODEX Comments		
Artichoke globe	1	CXL	2	Source of data: triadimefon, triadimenol		
Banana	0.2	CXL	0.2	Source of data: triadimenol		
Barley	0.5	CXL	TBD^3	Source of data: triadimefon, triadimenol		
Barley straw and fodder, Dry	5	CXL	TBD	Source of data: triadimefon, triadimenol		

^{2.} TBD = To be determined.

Table 15. Codex MRLs for Triadimenol and Applicable U.S. Tolerances.						
Codex			Reassessed			
Commodity (As Defined)	MRL ¹ (mg/kg)	Step	U.S. Tolerance (ppm)	CODEX Comments		
Chick-pea (dry)	0.05 (*)	CXL	2	Source of data: triadimefon		
Coffee beans	0.1 (*)	CXL	2	Source of data: triadimefon, triadimenol		
Currants, Black, Red, White	0.5	CXL	2	Source of data: triadimefon		
Eggs	0.05 (*)	CXL	Revoke	Source of data: triadimefon, triadimenol		
Fodder beet	0.05 (*)	CXL	2	Source of data: triadimefon		
Fodder beet leaves or tops	0.2	CXL	2	Source of data: triadimefon		
Fruiting vegetables, Cucurbits	2	CXL	2	Source of data: triadimefon, triadimenol		
Grapes	2	CXL	2	Source of data: triadimefon, triadimenol		
Hops, Dry	5	CXL	²	Source of data: triadimefon		
Mango	0.05 (*)	CXL	²	Source of data: triadimefon		
Meat (from mammals other than marine mammals)	0.05 (*)	CXL	Revoke	Source of data: triadimefon, triadimenol		
Milks	0.01 (*)	CXL	Revoke	Source of data: triadimefon, triadimenol		
Oat straw and fodder, Dry	5	CXL	TBD	Source of data: triadimefon, triadimenol		
Oats	0.2	CXL	TBD	Source of data: triadimefon, triadimenol		
Onion, Welsh	0.05 (*)	CXL	2	Source of data: triadimefon, triadimenol		
Peas (pods and succulent=immature seeds)	0.1	CXL	2	Source of data: triadimefon		
Peppers, Sweet	0.1	CXL	2	Source of data: triadimefon		
Pineapple	1 2	CXL	2	Source of data: triadimefon		
Pome fruits	0.5	CXL	 ²	Source of data: triadimefon, triadimenol		
Poultry meat	0.05 (*)	CXL	Revoke	Source of data: triadimefon, triadimenol		
Raspberries, Red, Black	0.5	CXL	2	Source of data: triadimefon		
Rye	0.2	CXL	TBD	Source of data: triadimefon, triadimenol		
Rye straw and fodder, Dry	5	CXL	TBD	Source of data: triadimefon, triadimenol		
Spring onion	0.05 (*)	CXL	2	Source of data: triadimefon		
Strawberry	0.1	CXL	2	Source of data: triadimefon		
Sugar beet	0.1 (*)	CXL	2	Source of data: triadimefon, triadimenol		
Sugar beet leaves or tops	1	CXL	2	Source of data: triadimefon, triadimenol		

Table 15. Codex MRLs for Triadimenol and Applicable U.S. Tolerances.								
Codex			Reassessed					
Commodity (As Defined)	MRL ¹ (mg/kg)	Step U.S. Tolerance (ppm)		CODEX Comments				
Tomato	0.5	CXL	2	Source of data: triadimefon				
Wheat	0.2	CXL	TBD	Source of data: triadimefon, triadimenol				
Wheat straw and fodder, Dry	5	CXL	TBD	Source of data: triadimefon, triadimenol				

- 1. Asterisk designates MRL set at the limit of quantitation.
- 2. The basic producer does not have registered uses of triadimenol on this commodity.
- 3. TBD = To be determined; crop field trial data requirements remain outstanding.

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CB No.: None

Subject: PP#3F2854: BaytanTM on Small Grains. Evaluation of residue data and analytical method.

From: A. Smith

To: H. Jacoby and Toxicology Branch

Dated: 8/1/83 MRID: None

CB No.: None

Subject: PP# 3F2854: BaytanTM on Small Grains. Amendment of 8/23/93.

From: A. Smith

To: H. Jacoby and Toxicology Branch

Dated: 1/4/84 MRID: None

CB Nos.: 4887, 4888, 4889, and 4890

Subject: PP#'s 3F2854, 4F3155, 5F3224, and FAP# 5H5458; Baytan Multiresidue Method Trial.

From: E. Haeberer

To: L. Rossi and Toxicology Branch

Dated: 2/23/89 MRID: 40969801

CB No.: 5221

Subject: PP8E3642: Triadimenol (Baytan or BAY KWG 0519) on Imported Bananas. Letter of March 28,

1989.

From: S. Malak

To: L. Rossi and Toxicology Branch

Dated: 5/16/89 MRID: 41051401

DP Barcode: None

Subject: Multiresidue Methods.

From: L. Edwards To: L. Sawyer, FDA

Dated: 6/30/92 MRID: 41976001 Summary Analytical Chemistry and Residue Data - TRED

DP Barcode: 314891

Triadimenol

DP Barcodes: D168542 and D178884

Subject: Triadimefon (109901): Storage Stability Data, PAM Multiresidue Methods, Product Chemistry

Data. CBRS Nos. 8566 and 9929.

From: S. Hummel

To: M. Wilhite/B. Sidwell

Dated: 12/22/92

MRIDs: 41976601, 41976602, and 42307801-42307803

DP Barcode: D174151

Subject: Triadimefon. List B Reregistration Case No. 2700/Chemical ID No. 109901. Raw data to upgrade

metabolism studies reviewed in Phase 4. Phase 5 Review of subject studies. CBRS No. 9422.

From: C. Swartz To: B. Sidwell Dated: 9/23/92

MRIDs: 42123400-42123404

DP Barcode: None

Subject: PP8E3642: Triadimenol (Baytan) on Imported Bananas. Comments on Draft Federal Register

Notice. CBTS #12171

From: M. Rodriguez
To: C. Giles-Parker

Dated: 7/20/93 MRID: None

DP Barcode: D194981

Subject: PP8E3642: Triadimenol (Baytan) on Imported Bananas. Amendment dated August 25, 1993.

Optical Configurations and Activities of Active Ingredient Isomers. (Response to CBTS #12171,

July 20, 1993). CBTS # 12533

From: M. Rodriguez

To: C. Giles-Parker/J. Stone

Dated: 9/23/93 MRID: None

DP Barcode: D194719

Subject: Triadimefon. List B Reregistration Case No. 2700/Chemical ID No. 109901. Submission of Raw

Data to Upgrade Cucumber and Tomato Metabolism Studies. CBRS No. 12515

From: C. Swartz To: B. Sidwell Dated: 10/20/93

MRIDs: 42798900 and 42798901

DP Barcode: D194783

Subject: Triadimefon. Storage Stability Study. Reregistration Case No. 2700. Chemical No. 109901. CBRS

#12528.

From: Steven A. Knizner

To: M. Wilhite Dated: 11/7/93 MRID: 42857401

DP Barcode: D194786

Subject: Triadimefon. Poultry Metabolism Study. Reregistration Case No. 2700. Chemical No. 109901.

CBRS #12530.

From: Steven A. Knizner

To: M. Wilhite
Dated: 11/2/93
MRID: 42864901

Summary Analytical Chemistry and Residue Data - TRED

DP Barcode: D194819

Triadimenol

Subject: Triadimefon. Ruminant Metabolism Study. Reregistration Case No. 2700. Chemical No. 109901.

DP Barcode: 314891

CBRS #12514.

From: Steven A. Knizner

To: M. Wilhite Dated: 11/2/93 MRID: 42856801

DP Barcode: D186937

Subject: Triadimefon. Confined Rotational Crop Study. Reregistration Case No. 2700. Chemical No.

109901. CBRS #11212.

From: Steven A. Knizner

To: M. Wilhite Dated: 11/3/93 MRID: 42613301

DP Barcode: D194676

Subject: Triadimefon. Wheat Metabolism Study. Reregistration Case No. 2700. Chemical No. 109901.

CBRS #12527.

From: Steven A. Knizner

To: M. Wilhite Dated: 11/3/93 MRID: 42853401

DP Barcode: D189881

Subject: ID#: 003125-UEU. Triadimenol (Baytan 2.6 FS) for Use as a Seed Treatment in or on Wheat,

Barley, and Oats. Evaluation of Analytical Method and Magnitude of the Residue Data. CBTS No.

11690.

From: D. Davis

To: J. Stone/C. Giles-Parker and J. Fleuchaus

Dated: 11/3/93

MRIDs: 42696308, 42696309, 42712101

DP Barcode: None

Subject: Triadimefon. Addendum to Wheat, Ruminant, and Poultry Metabolism Studies and Confined

Rotational Crop Study. Reregistration Case No. 2700. Chemical No. 109901.

From: Steven A. Knizner

To: M. Wilhite Dated: 12/9/93

MRIDs: 42853401, 42856801, 42864901, and 42613301

DP Barcode: D199645

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Data. CBTS No. 13268.

From: D. Davis

To: J. Stone/C. Giles-Parker

Dated: 3/7/94 MRID: None

Summary Analytical Chemistry and Residue Data - TRED

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Triadimenol

Subject: Triadimefon. Data Submitted to Upgrade Ruminant and Poultry Metabolism Studies and Analysis

of Tissues from Metabolism Study with Analytical Enforcement Method. Reregistration Case No.

DP Barcode: 314891

2700. Chemical No. 109901. CBRS #14659

From: Steven A. Knizner

To: M. Wilhite Dated: 12/16/94

MRIDs: 43418301, 43418302, and 43418303

DP Barcode: D210160

Subject: Triadimefon. Meat, Milk, Eggs Storage Stability Study. Reregistration Case No. 2700. Chemical

No. 109901. CBRS #14826

From: S. Knizner
To: M. Wilhite
Dated: 2/23/95
MRID: 43462401

DP Barcodes: D227403, D227497, D227543

Subject: Residue Analytical Methods, Storage Stability Data

From: J. Punzi To: B. Chambliss Dated: 7/13/00

MRIDs: 43870101, 44038901, 44041001, 44041002

DP Barcode: None DEB No.: 5865

Subject: PP#9F3802. Triadimenol in or on cotton seed and cotton forage.

From: L. Rodriquez
To: S. Lewis
Dated: 3/12/1990
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Subject: Triadimenol. Field Corn, Cotton, and Wheat Processing Studies

From: S. Ary
To: R. Griffin
Dated: 10/14/2005

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To: R. Griffin and J. Pates

Dated: 11/23/2005 MRID: None

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Appendix 1. Food/Food Use Patterns for Triadimenol.

This document was originally prepared by the Biological and Economic Analysis Division (BEAD). Current as of: 3/2/2005.

SITE NAME	LIMITATIONS							
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	MRI	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)		
BARLEY	40 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food or feed. Do not contaminate water, food, or feed by storage or disposal. Do not place in locations accessible to children, pets or domestic animals. Do not use seed for food, feed or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Keep out of lakes, streams, and ponds.							
Seed Seed treatment	.03125 lb cwt	NS	NS NS	NS	12 h			

SITE NAME	LIMITATIONS							
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	MRI	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)		
Mist-type seed treater/Slurry-type seed treater								
CORN (UNSPECIFIED)	45 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food or feed. Do not contaminate water, food, or feed by storage or disposal. Do not place in locations accessible to children, pets or domestic animals. Do not use seed for food, feed or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Keep out of lakes, streams, and ponds.							
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	.0625 lb cwt	NS	NS NS	NS	12 h			
COTTON (UNSPECIFIED)	Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food, or feed by storage or disposal. Do not enter treated areas without protective clothing until sprays have dried. Do not use seed for food, feed or oil purposes. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Groundwater restriction. This pesticide is toxic to aquatic invertebrates. This product is toxic to fish. Geographic disallowable: Other							
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	.06211 lb cwt	NS	NS NS	NS	24 h			
OATS	40 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to							

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	MRI	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)	
	intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food or feed. Do not contaminate water, food, or feed by storage or disposal. Do not place in locations accessible to children, pets or domestic animals. Do not use seed for food, feed or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Keep out of lakes, streams, and ponds.						
Seed Seed treatment Slurry-type seed treater	.03125 lb cwt	NS	NS NS	NS	12 h		
RYE	40 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate food or feed. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food or feed. Do not contaminate water, food, or feed by storage or disposal. Do not place in locations accessible to children, pets or domestic animals. Do not use seed for food, feed or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Keep out of lakes, streams, and ponds.						
Seed Seed treatment Mist-type seed treater/Slurry-type seed treater	.03125 lb cwt	NS	NS NS	NS	12 h		
WHEAT	40 day(s) pregrazing interval. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not contaminate food or feed.						

SITE NAME	LIMITATIONS						
Application Timing (for any Reg.# at any rate) Application Type (for any Reg.# at any rate) Application Equipment (for any Reg.# at any rate)	Max. Single Appl. Rate to a Single Site	Max. Seasonal Rate	Max. # Apps/ cc & yr	MRI	REI	PHI/PGI/PSI Use Limitations (May not apply to all Reg. #s)	
	Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water, food or feed. Do not contaminate water, food, or feed by storage or disposal. Do not place in locations accessible to children, pets or domestic animals. Do not use seed for food, feed or oil purposes. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Keep out of lakes, streams, and ponds.						
Seed Seed treatment Slurry-type seed treater	.03125 lb cwt	NS	NS NS	NS	12 h		

PRODUCT NUMBERS CONTAINED IN THIS REPORT

000264-00742, 000264-00760, 002935-00459, 007501-00091, 007501-00186

HOMEOWNER PRODUCTS CONTAINED IN THIS REPORT

None

HEADER ABBREVIATIONS

Site Name - The site name refers to the entity (crop, building, surface or article) where a pesticide is applied and/or which is being protected.

Limitations - Precautionary statements related to the use of the product(s).

Application Timing - The timing of pesticide application and is the primary application sort (not aggregated).

Application Type - The type of pesticide application (aggregated).

Application Equipment - The equipment used to apply pesticide (aggregated).

Max. Single Appl. Rate to a Single Site - Maximum Dose for a single application to a single site. System calculated.

Max Seasonal Rate - The maximum amount of pesticide that can be applied to a site in one growing season (/cc) and during the span of one year (/yr).

Max. # Apps/cc & yr - Maximum Number of Applications per crop cycle and per year.

M R I - Minimum Retreatment Interval (days) (at any rate). The minimum interval between pesticide application (days).

R E I - ReEntry Interval - The minimum amount of time that must elapse before workers can reenter a treated area.

PHI/PGI/PSI Use Limitations (May not apply to all Reg.#s) - Preharvest/Pregrazing/Preslaughter Interval use limitations pertinent to the application.

Current As Of: - The label data for the listed products in this report is current as of this date.

ABBREVIATIONS

- AN As needed
- NA Not Applicable
- NS Not Specified (on label)
- (L) The dosage information provided is from the label in terms of product (e.g., ounces, gallons, or pounds of the product) because there was insufficient information (e.g., missing density, area, or active ingredient percentages) to provide converted dosage information. This report provides active ingredient

percentage in the product for the reported chemical for all unconverted label dosage information if this information is available. This active ingredient percentage information is displayed next to the form code abbreviations (e.g., 80% WP).

UC - Unconverted due to lack of data (on label).

APPLICATION RATE

W : PPM calculated by weightV : PPM calculated by volume

U : Unknown whether PPM is given by weight or by volume

~ : The dosage information includes a contribution from one or more (TQ, CL, BR, I) active ingredients.

cwt : Hundred Weight

nnE-xx: nn times (10 power -xx), for instance, "1.234E-04" is equivalent to ".0001234"