1-31-91 R.F.

Case No.: 2700
Chemical No(s).: 109901

DEB TRANSMITTAL SHEET FOR PHASE 4 REVIEWS

Transmitted to HED on 10/09/90
Case name: Triadimefon
Chemical name(s): 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone
Data submitter(s): Mobay Corporation

CRM: Franklin Rubis Phone #: 308-8184

Issues/flags:

This action contains a request for a DATA WAIVER (X)
TIME EXTENSION ( )
ALTERED/DELETED USE (X)

Other: (1) Registrant is not supporting the stone fruit use. (2) Use data from LUIS report of 10/3/90 and labels 3125-320 and 3125-340.

Branch: CBRS, Phase 4 Review Team S.R. Funk
Reviewed by: Stephen R. Funk Date: 01/24/91

1/28/91

Approvals:

Section Head: Andrew Rathman Date: 1/29/91

Branch Chief: Edward Zager Date: 1/31/91

cc: Part B Reregistration File, RF, Circ., S. Funk, C. Furlow (PIB, FOD), Betsy Grim (EFED).

1/17

Response, by Guideline

Guideline #: 171-4(a) Description: Nature of residue - plants
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188031, Summary 92188030 (wheat); 92188026, 92188025 Summary (apples); 92188033, 92188032 Summary (grapes); 92188028, 92188029, Summary 92188027 (tomatoes, cucumbers). Wheat study is inadequate. Characterization was by tlc only, not confirmed. Low residues on wheat grain were not characterized; higher application rates are needed. For cucumber and tomato studies, raw data (dpm, sample weights) and GC/MS results must be submitted. For the apple and grape studies, raw data and representative sample tlc chromatograms must be supplied.

Data gap:
The registrant must provide a new plant metabolism study. Triadimefon radiolabelled in a non-labile part of the molecule such as ^{14}C in the phenyl moiety should be applied to wheat foliage reflecting the currently registered use. The specific activity and/or application rate should be high enough to allow for adequate identification of the metabolites/degradates, including residues in/on wheat grain. Characterization by one technique (such as tlc) must be confirmed by a second technique (hplc, gc, gc/ms, etc.). The plant material from the metabolism study should be tested using the data collection method(s) and enforcement analytical method(s). Raw data and sample chromatograms must be submitted for the new study and for previously submitted apple, grape, cucumber, and tomato studies.

Guideline #: 171-4(b) Description: Nature of residue - animals
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188039, Summary 92188038 (Poultry); 92188037, Summary 92188036 (Swine); 92188035, Summary 92188034 (Cow). Poultry study is unacceptable for review. The radiolabelled diet must be fed for a minimum of three consecutive days. The swine study may be acceptable for review, if the registrant supplies supporting chromatograms (tlc, gc confirmatory chromatograms). The cow study is unacceptable. Residue levels were too low to permit characterization in muscle,

fat, and milk. Characterization of residues in liver and in kidney were incomplete. An exaggerated level (300 - 400 X theoretical) should be fed for at least three days to attempt to achieve radiolabelled levels adequate for characterization. Evidence (chromatograms, raw data) must be submitted.

Data gap:
The registrant must provide livestock (poultry and ruminants) metabolism studies. Triadimefon radiolabelled in a non-labile part of the molecule such as ^{14}C in the phenyl moiety should be fed to the livestock for a minimum of three days. Orally treated test animals must be sacrificed within 24 hours of the final dose. The dose administered and the specific activity should be high enough to allow for adequate identification of the metabolites/ degradates. The tissues from the metabolism study should be tested using the data collection method(s) and enforcement analytical method(s).

Guideline #: 171-4(c) Description: Res. analyt. method - plant
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188043, 92188041, 92188040, Summary 92188042. Submission presented for triadimefon and three hydroxy metabolites in/on barley and wheat straw, forage, and grain. The study is acceptable for review purposes as a data collection method. Validation data (fortification recovery) must be presented for other plant matrices, such as apples, almonds, cucurbits, sugar beets, and grapes. It may also be acceptable as a regulatory method, but independent laboratory validation and a confirmatory method are needed. The method has not been validated by either an independent laboratory or the EPA. A modification of the method, eliminating certain clean-up and column chromatography steps, provides a rapid method for the determination of triadimefon and one metabolite, KWG0519. This might be an acceptable regulatory method for processed food/feed commodities, where triadimefon and KWG0519 are the only regulated residues (40 CFR 185.800; 186.800). Again, independent validation and a confirmatory method are required. A regulatory method exists in PAM II, Methods I and II for animal commodities. The method is applicable to plants, but validation data are needed. PAM I 232.4 (Protocol D) provides adequate recovery for the parent and one metabolite. The other two metabolites (KWG-1342 and KWG-1323) should be tested.

Data gap:
The registrant must submit regulatory analytical method(s) for the determination of triadimefon and its metabolites (KWG-0519 or triadimenol or Baytan, KWG-1342 or 1-(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol, and KWG-1323 or 1-

(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone) in/on wheat (straw, forage, grain), barley (straw, forage, grain), apples, almonds, cucurbits, sugar beets, pineapples, and grapes. The methods summarized in MRID 92188042 are acceptable for review as data collection methods, but must be validated (fortification recovery) for apples, almonds, cucurbits, sugar beets, pineapples, and grapes. If new metabolites (which require regulation) are found in the new plant metabolism studies, then analytical method(s) must be developed for them as well. Regulatory methods must include a confirmatory technique. Any regulatory methods submitted (including the proposed regulatory methods of MRID 92188042) will require an independent method validation as described in PR Notice 88-5 (July 15, 1988). The triadimefon metabolites KWG-1342 and KWG-1323 and any newly identified regulated metabolites must be tested through multi-residue Protocol(s) C, D, and E, and representative (including the most difficult) plant matrices must be tested.

Guideline #: 171-4(d) Description: Res. anal. method - animals
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188045, 92188046, 92188047, 92188048, 92188044 Summary. Two methods (and variations) are reported in the summary. A Florisil-cleaned extract is analyzed by gas chromatography (N-P detector) for triadimefon and KWG0519. Acceptable recovery data are reported for bovine liver, kidney, muscle, fat, and milk and for poultry liver, gizzard, muscle, fat, skin, and eggs. A second method determines via GC/MS triadimefon and four hydroxy metabolites as a derivative of 4-chlorophenol. Note that the method determines the sum total of triadimefon and the regulated metabolites and not individual regulated compounds. It is the regulatory method, PAM II, Methods I and II. The registrant presents acceptable recovery data for bovine liver, kidney, muscle, fat, and milk and for poultry liver, gizzard, muscle, fat, skin, and eggs. The summary and reformats are acceptable for review, both as data collection (both methods) and enforcement (GC/MS method only) methods. The metabolites KWG-1342 or 1-(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol, KWG-1323 or 1-(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone), and KWG-1640 or 4-(4-chlorophenoxy)-4-(1H-1,2,4-triazol-1-yl)-3-hydroxy-2,2-dimethylbutanoic acid need to be tested through the multi-residue Protocols C, D, and E, and representative animal commodities need to be tested.

Data gap:

If new metabolites (which require regulation) are found in the new animal metabolism studies, then analytical method(s) must be developed for them as well. Any regulatory methods submitted will require an independent method validation as described in PR Notice 88-5 (July 15, 1988). The metabolites KWG-1342 or 1-(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol, KWG-1323 or 1-(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone), and KWG-1640 or 4-(4-chlorophenoxy)-4-(1H-1,2,4-triazol-1-yl)-3-hydroxy-2,2-dimethylbutanoic acid need to be tested through the multi-residue Protocols C, D, and E, and representative animal commodities (including the most difficult) must be tested.

Guideline #: 171-4(e) Description: Storage stability
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188053, 92188052, Summary 92188051. Submissions cover storage stability for apples (peel), potatoes, grapes, and wheat forage. Storage stability of two metabolites are reported for wheat grain. Storage stability studies are needed for wheat (straw, grain, grain dust, bran, flour, middlings, shorts), barley (grain, grain dust, straw, forage, hulls, bran, flour, and pearl barley), sugar beets (root, tops, pulp, molasses, refined sugar), almonds (nutmeat, hulls), pineapple, pear, cattle (milk), cucurbits (such as cucumber), processed grape products (raisin, wet and dry pomace, raisin waste, juice), raspberries, seed grass, poultry (meat, fat, eggs), and chick peas.

Data Gap:
Storage stability studies must be conducted on all crops and processed products for which a field trial and/or processing study has been (or will be) conducted, as well as representative livestock commodities. Storage stability studies are needed for wheat (straw, grain, grain dust, bran, flour, middlings, shorts), barley (grain, grain dust, straw, forage, hulls, bran, flour, and pearl barley), sugar beets (root, tops, pulp, molasses, refined sugar), almonds (nutmeat, hulls), pineapple, pear, cattle (milk), cucurbits (such as cucumber), processed grape products (raisin, wet and dry pomace, raisin waste, juice), raspberries, seed grass, poultry (meat, fat, eggs), and chick peas. Use of field-weathered samples is strongly recommended. Storage conditions must reflect the storage conditions of the treated samples (from the field trial and processing studies) with respect to temperature, length of storage, containers, lighting, etc. If there are any metabolites and/or degradates included in the tolerance expressions, then they must be tested as well. The chosen intervals must allow for unforeseen delays in sample storage.

Guideline #: 171-4(f) Description: Mag. res. - potable water
Is requirement applicable? (Y/N): N
Does the summa/available information indicate that the MRID is a candidate for Phase 5 review?: ___
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:

Data gap: None

Guideline #: 171-4(g) Description: Magnitude residue - fish
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: ___
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:

Data gap: None

Guideline #: 171-4(h) Description: Mag. res. - irrigated crop
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: ___
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:

Data gap: None

Guideline #: 171-4(i) Description: Mag. res. - food handling
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: ___
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:

Data gap: None

Guideline #: 171-4(j) Description: Mag. meat/milk/poultry/eggs
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )

Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188055, 92188057, Summary 92188054, Summary 92188056.
Dairy cattle were fed a 1:1 mixture of triadimefon and triadimenol at levels corresponding to 0X, 0.34X, 1X, and 3.4X the maximum dietary burden based on a 105 ppm tolerance for triadimefon and its regulated metabolites in/on grass seed straw. The levels correspond to 0X, 2.4X, 7X, and 24X the maximum dietary burden based on the 15 ppm tolerance for triadimefon and its regulated metabolites in/on wheat forage. Kidney, liver, muscle, fat, and milk were analyzed for the combined residues of triadimefon and its regulated metabolites. The study is acceptable for review, pending submission of adequate storage stability data (milk).
Poultry (chicken hens) were fed a 1:1 mixture of triadimefon and triadimenol at levels corresponding to 0X, 10X, 25X, 75X, and 250X the maximum dietary burden based on a 1 ppm tolerance for triadimefon and its regulated metabolites in/on wheat or barley grain. Muscle, fat, liver, skin, gizzard, and eggs were analyzed for the combined residues of triadimefon and its regulated metabolites. The study is acceptable for review, pending submission of adequate storage stability data (poultry tissue, eggs).
Data gap:
Storage stability studies must be conducted for triadimefon and its regulated metabolites in milk, poultry tissue, and eggs. Storage conditions should reflect conditions used in the magnitude of residue studies (See 171-4(e)).

Triadimefon Use Information				
Commodity	Max Rate (lb a.i./A) Single	Max Rate (lb a.i./A) Seasonal	PHI (days)	Equipment
Almond	1.0	2.0	-	A, G
Apple	0.25	0.75	0[1]	A, G
Barley	0.25	0.5	21	G, A
Chick Pea[2]				
Cucurbit	0.125	0.5	0	A, G
Grape	0.188	0.56	14	A, G
Grass, seed	0.5	1.0	5[3]	A, G
Pear	0.25	0.75	0[1]	A, G
Pineapple	0.417 lb/ 100 gal water	-	0[4]	-[4]
Raspberry	0.125	0.875	1	G, A
Sugar Beet	0.5	0.5	15, 30[5]	A, G
Wheat	0.25	0.5	21	G, A

[1] Grazing restriction. [2] Foreign use. Translated label(s) requested. [3] Chaff and straw may be used for feed. Forage, green crop, and seed may not be used as feed. Regrowth may be grazed 11 weeks after last application. [4] Postharvest 3 minute fruit dip or spray. [5] 15 day for broadcast spray application, 30 day for spray directed into the whorl.

Guideline #: 171-4(k/l) Description: Wheat field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188074, Summary 92188064. Crop field trials were conducted in NY, ND, TX, CA, MT, IN, KS, and GA. Aerial applications were conducted in ND and MT. Except in TX, the minimum ground application volume of 10 gal water per acre was not used, but rather 23 - 86 GPA. Additional aerial application studies are needed, additional geographic areas (NW US) must be represented, and a ground application study must be conducted with minimum water of dilution. Grain dust must be analyzed in the new field trials. Storage stability studies are required for wheat grain, straw, grain dust and processed commodities.
A processing study is required. The study submitted did not determine triadimefon and its metabolites in/on middlings. The registrant's claim that middlings are a mixture of shorts and bran is unacceptable. Middlings also contain wheat germ, flour, and offal.

Data gap:
Data depicting residues of triadimefon and the regulated metabolites in/on wheat . The 50% a.i. WP or the 50% a.i. DF formulation must be applied at the maximum label rate of 4 oz. a.i./acre, in two applications (8 oz. a.i. total per season), and with a 21 day PHI. The use of aerial equipment must be represented in TX, WA or OR, CA, NY, IN, KS, and GA. The use of ground equipment with the minimum amount of dilution water (10 GPA) must be represented in WA or OR, in a side-by-side trial with the aerial application. Grain dust must be analyzed as well as grain, straw, and forage.
A processing study must be conducted for wheat. Wheat with detectable residues of the parent and the regulated metabolites should be processed into middlings to determine the residue concentration or reduction factor(s).
Note: exaggerated rates may be necessary.

Guideline #: 171-4(k/l) Description: Barley field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver(X) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
MRID Nos.: 92188076, Summary 92188059. Studies were conducted in ND, ID, KS, NY, IN, and GA. Additional studies are needed in CA and WA or OR, but data from requested wheat studies in WA or OR may be translated to barley. Additional aerial application studies are

needed, but data from requested wheat studies may be translated to barley. Barley grain dust should be analyzed in any new field trials. A barley processing study is needed.
The registrant requests a waiver from the requirement to perform a barley processing study, claiming that wheat processing data should be translatable to barley. Barley processing is significantly different from wheat processing, and the application to barley is late season. Therefore, the waiver request is denied.

Data gap:
Data depicting residues of triadimefon and the regulated metabolites in/on barley. The 50% a.i. WP or 50% a.i. DF formulation must be applied at the maximum label rate of 4 oz. a.i./acre, with two applications (8 oz. a.i. total per season), the minimum amount of dilution water (10 GPA ground, 5 GPA aerial), and a 21 day PHI. The use of aerial and ground equipment must be represented in separate side-by-side tests in WA or OR, and CA. Alternatively, the requested wheat field trial data for WA or OR may be translated to barley. Barley grain dust, as well as grain, straw, and forage, must be analyzed.
A processing study must be conducted for barley. Late season foliar application of triadimefon to barley and the differences in wheat and barley processing preclude translation of wheat processing data to barley. Barley with detectable residues of the parent and the regulated metabolites should be processed into hulls, bran, flour, and pearl barley to determine the residue concentration or reduction factor(s). If the barley is treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the rac, then processing studies are not required.
Note: exaggerated rates may be necessary.

Guideline #: 171-4(k) Description: Raspberries field trials
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID No.: Summary 92188061. The submission is deficient in three aspects: (1) Application was in 200 GPA water; label specifies 20 GPA water; (2) analyses were not conducted for two minor metabolites; (3) storage stability was not determined. This is a minor use classification; therefore, the submission will be acceptable for review if a storage stability study is supplied.

Data gap:
A storage stability study is required for raspberries bearing detectable levels of triadimefon and its regulated metabolites (see 171-4(e)).

Guideline #: 171-4(k/l) Description: Stone fruit field trials/process
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other (X)
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
Registrant has submitted amended labels for 003125-00340 and 003125-00320 with stone fruit uses deleted. LUIS and most recent labels indicate that such uses were deleted previously.

Data gap:
None, assuming another registrant, government agency, or user group does not support this use.

Guideline #: 171-4(k) Description: Grass field trials
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188025, Summary 92188062. Nine ground application studies were conducted in Oregon, 6 of which were at the maximum application rate and 1 of which was at the maximum application rate and minimum GPA water. Aerial applications, additional geographic representation, ground applications with the minimum GPA water (20 GPA), and storage stability studies are needed. The practicality of the various feeding and/or grazing restrictions will be reevaluated during Phase 5.

Data gap:
Data depicting residues of triadimefon and the regulated metabolites in/on seed grass (straw, cleanings, forage regrowth). The 50% a.i. WP or 50% a.i. DF formulation must be applied at the maximum label rate of 8 oz. a.i./acre in 20 GPA water (ground) or in 7 GPA water (aerial) in two applications 14 days apart (16 oz. a.i. total) with a 5 day PHI. The use of aerial and ground equipment must be represented in separate tests in KY, KS or MO or IA or NE or ND or SD or MN, and AZ or CA. The use of aerial equipment must be represented in OR. These states represent the major seed grass production regions. Storage stability data are required (see 171-4(e)).

Guideline #: 171-4(k) Description: Almond field trials
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )

Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188078, Summary 92188058. Four trials were made in CA, all high volume ground applications at 5% bloom to full bloom stage. Two applications, each 125% of maximum label rate, were made. CA is the major domestic almond production region. A storage stability study is needed.

Data gap:
None, pending acceptable storage stability data for almonds (see 171-4(e)).

Guideline #: 171-4(k) Description: Chick peas field trials
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188070, Summary 92188060. Field trials were conducted in Mexico, a major chick pea producing region. Dried chick peas, the only rac imported, were analyzed for triadimefon and one metabolite (triadimenol). A translated label is needed to determine if conditions leading to maximum residues were employed.

Data gap:
Registrant must submit an English translation of label(s) for the application of triadimefon to chick pea plants. The report submitted may be acceptable for review if maximum application rate, maximum number of applications, minimum dilution water, and minimum PHI were observed. A storage stability study is needed for dried chick peas (see 171-4(e)).

Guideline #: 171-4(k/l) Description: Sugar beets field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
MRID Nos.: 92188073, 92188069, Summary 92188063, and Summary 92188065. Triadimefon was applied to sugar beets at the maximum label rate of 8 oz. a.i./acre, using either single broadcast or band over whorl spray application. The PHI was 27 - 31 days for the band over whorl application (30 day label PHI) and 15 - 17 days for band application (15 day label PHI). Trials were conducted in MN, AZ, ND, CO, TX, CA, ID, and MI. This represents 85% of domestic sugar beet production. The field trial study is acceptable for review, pending

submission of storage stability data for sugar beet roots and tops. Simulated commercial techniques were used to process sugar beets into wet pulp, dry pulp, molasses, refined sugar, clarified juice, raw sugar, and lime cake. All fractions were analyzed for triadimefon, triadimenol, and KWG-1342. The study is acceptable for review, pending submission of storage stability data for dry pulp, molasses, and refined sugar.

Data gap:
Storage stability studies must be conducted for sugar beet roots, sugar beet tops, and processed commodities (see 171-4(e)).

Guideline #: 171-4(k/1) Description: Apple field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
Registrant has committed to supply a new study.

Data gap:
Data depicting residues of triadimefon and the regulated metabolites in/on apples. The 50% a.i. WP or 50% a.i. DF formulation must be applied at the maximum label rate of 4 oz. a.i. per acre in three applications (12 oz. a.i. total) at 7 day intervals. The final application should be on the day of harvest. The use of aerial and ground (both high volume and low volume) equipment must be represented in separate tests. The tests must be conducted in CA, MI, NY, PA or WV, VA or NC, and WA or OR, which represent the major apple production regions.
A processing study must be conducted for apples. Apples with detectable residues of the parent and the regulated metabolites should be processed into juice and wet and dry pomace to determine the residue concentration or reduction factor(s). If the apples are treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the rac, then processing studies are not required.
Note: exaggerated rates may be necessary.

Guideline #: 171-4(k/1) Description: Pineapple field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other ( )

Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
The registrant has committed to supply a new study.

Data gap:
Data depicting residues of triadimefon and the regulated metabolites in/on pineapples. The 50% a.i. DF formulation must be applied at the maximum label rate of 6.667 oz. a.i. in 100 gallons of water as a 3 minute postharvest dip for fresh pineapple.
A processing study must be conducted for pineapples. Pineapples with detectable residues of the parent and the regulated metabolites should be processed into bran and juice to determine the residue concentration or reduction factor(s). If the pineapple is treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the rac, then processing studies are not required.

Guideline #: 171-4(k) Description: Pears field trials
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
Registrant has committed to supply a new study.

Data gap:
Data depicting residues of triadimefon and the regulated metabolites in/on pears. The 50% a.i. WP or 50% a.i. DF formulation must be applied at the maximum label rate of 4 oz. a.i. per acre in three applications (12 oz. a.i. total) with a 0 day PHI. The use of aerial (5 GPA water) and ground (20 GPA water and 400 GPA water) equipment must be represented in separate tests. The tests must be conducted in CA, MI, NY, and WA, which represent the major pear production regions.

Guideline #: 171-4(k/l) Description: Grapes field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
Registrant has committed to supply a new study.

Data gap:

Data depicting residues of triadimefon and the regulated metabolites in/on grapes. The 50% a.i. WP or the 50% a.i. DF formulation must be applied at the maximum label rate of 3 oz. a.i. per acre for three applications (9 oz. a.i. total) through veraison with a 14 day PHI. The use of aerial (5 GPA water) and ground (20 GPA water) equipment must be represented in separate tests. The tests must be conducted in CA, NY, WA, MI, and NC, which represent the major grape production regions.
A processing study must be conducted for grapes. Grapes with detectable residues of the parent and the regulated metabolites should be processed into raisins, wet and dry pomace, raisin waste, and juice to determine the residue concentration or reduction factor(s). If grapes are treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the rac, then processing studies are not required.
Note: exaggerated rates may be necessary.

Guideline #: 171-4(k) Description: Cucurbits field trials
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
Registrant has committed to generate a new study.
Data gap:
Data depicting residues of triadimefon and the regulated metabolites in/on cucurbit vegetables group. The 50% a.i. WP or the 50% a.i. DF formulation must be applied at the maximum label rate of 2 oz. a.i. per acre in 4 applications (8 oz. a.i. total) at 14 day intervals and a 0 day PHI to three representative rac's (cucumbers, melons (cantaloupe or muskmelon), summer squash). The use of aerial and ground equipment must be represented in separate tests. The tests must be conducted in CA, TX or AZ, IN, MI, GA or SC for melons, CA, FL, TX, NJ or MA or NY, OR, GA or SC, and MI for summer squash, and CA, FL, TX, MI, NY or NJ, NC or SC, and OH for cucumbers, which represent the major respective cucurbit production regions.

ADDITIONAL COMMENTS:

The registrant is advised to consult the Subdivision O Residue Chemistry Guidelines, the Standard Evaluation Procedures, the Data Reporting Guidelines, and the Phase 3 Technical Guidance concerning conduct of residue chemistry studies. If the registrant has additional concerns they are advised to submit a protocol for CBRS review.

PRODUCT CHEMISTRY

Case No.: 2700 Case Name: Triadimefon
Chemical No(s).: 109901
Chemical Name(s): 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone
Registrant: Mobay Corporation

Guideline Number	Is requirement applicable?	Does summary or available information indicate MRID is a candidate for Phase 5 review?	Are additional data required?	MRID Number[1]
61-1	Y	Y	N	92188001
61-2(a)	Y	P	Y[2]	92188001
61-2(b)	Y	Y	N	92188001
62-1	Y	Y	N[3]	92188067
62-2	Y	Y	N	92188067
62-3	Y	P	Y[4]	92188067
63-2	Y	Y	N	92188004
63-3	Y	Y	N	92188004
63-4	Y	Y	N	92188004
63-5	Y	Y	N	92188004
63-6	N			
63-7	Y	Y	N	92188004
63-8	Y	Y	N	92188004, 41616001
63-9	Y	N/A	Y[5]	
63-10	N			
63-11	Y	P	Y[6]	41616001
63-12	Y	Y	N	92188004
63-13	Y	P	Y[7]	41616001

Key: Y=yes; N=no; I=a decision cannot be made at this time; S=fully satisfies requirement; P=partially; N/A=not applicable; U=unsatisfactory.

1 MRID No. is not listed if study or summary are found to be inadequate.

2 Deficiencies: flowchart of intended reactions; relative (molar) amounts of reactants and order of addition; equipment description.

3 Previously determined that analysis of TGAI for halogenated dibenzo-p-dioxins/dibenzofurans is not required (02/23/90 Memo, S. Funk, DEB No. 6101).

4 Accuracy and precision data must be presented for analytical methods used to verify certified limits for the active ingredient and each impurity (≥ 0.1% w/w).

5 New study to be submitted.

6 Temperature of determination and technique/equipment used to control temperature must be described. Title of submission

7 refers to 20 degrees C.
Data are required on the thermal stability of triadimefon at ambient and elevated temperatures.