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

JUN 14 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP No. 5F04591, **Propiconazole** on the berry crop grouping, carrots, and onions (green and dry bulb). Chemical No. 122101. D219664, CBTS No. 16294, MRIDs 43786401, 43786401, 43786402, 43786403, 43786404, PRAT CASE No. 287013.

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Ciba-Geigy proposes tolerances for the fungicide propiconazole (CGA 64250), (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole), and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA), expressed as parent as follows:

Berry, crop group	1.0 ppm
Onions, green	8.0 ppm
Onions, dry bulb	0.3 ppm
Carrots	0.2 ppm

Tolerances are established for numerous plant and animal commodities [40 CFR 180.434(a), (b) and (c)], ranging from 5 ppm in/on celery to 0.05 ppm in milk. Pending and time-limited tolerance petitions for propiconazole include almonds, peanuts, oats, the stone fruit crop group, dry beans and soybeans, and inadvertent/rotational tolerances for alfalfa and sorghum residues.

Conclusions

1. Product chemistry guidelines 61-2 & 63-2, -3, -4, -6, -7, -10, -11, & -12 are satisfied. Guideline 63-13, the test for stability, is an outstanding data gap, because the sensitivity of the a.i. to metal ions must be determined. This deficiency will be resolved in reregistration.

2a. The proposed label for green and dry bulb onions, onions grown for seed, and carrots, states that propiconazole is to be used in "sufficient water to provide sufficient coverage." This label is inadequate and should be modified to specify the minimum volume of water necessary to ensure coverage.

2b. The following restriction should be added to the proposed use directions for carrots, "Do not tank mix with any pesticidal product which does not have a registered use."

2c. A revised Section B is needed stating the amount of propiconazole ai applied expressed as lbs ai/A.

2d. No PHI was included on the proposed label for use of propiconazole on blackberries or raspberries, although all of the field data represent a PHI of 30 days. A PHI of 30 days should be specified on the label. A revised Section B is needed.

3. The label proposes a use on onions grown for seed which is identical to the proposed uses on green and dry bulb onions. Residues resulting from the seed use are expected to be considerably less than those from the direct uses on green and dry bulb onions, therefore, no residue data are needed for onions grown for seed use.

4a. Ciba-Geigy has proposed a new plant metabolism study with phenyl-^{14}C-propiconazole on celery, to supplement metabolism data on peanuts, grapes, corn, winter wheat, lettuce and carrots.

4b. The metabolism of propiconazole in/on plants and animals is tentatively understood, pending receipt of additional metabolism studies required for reregistration. The residues of concern are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent (PP#8F3674, 12/14/88).

4c. An additional metabolism study is necessary on a tuber crop, i.e., carrots.

5a. No animal feed items are associated with use of propiconazole on berries or green onions, dry bulb onions, or onions grown for seed. Secondary residues of propiconazole in meat, milk,

poultry, and eggs are not expected to occur as a result of these proposed uses.

5b. Carrot culls are feed items for beef and dairy cattle, and breeding and finishing swine. However, secondary residues in animal commodities are not expected to exceed existing tolerances as a result of the proposed use of propiconazole on carrots.

6a. The current enforcement method for plants is a single moiety analytical method which detects residues as 2,4-dichlorobenzoic acid methyl ester and reports them as propiconazole equivalents. Ciba-Geigy's Analytical Method AG-454 has been validated by EPA's Analytical Chemistry Laboratory. Pending publication in PAM II, the analytical method is available from PRPRB/FOD.

6b. If additional metabolites of concern are identified, which are not determined by the single moiety method, a new analytical method will be needed to regulate residues of concern, including laboratory independent and petition method validation (ILV and PMV).

6c. CBTS tentatively concludes that adequate enforcement methods are available for the proposed tolerances in plant commodities, pending receipt of the new metabolism studies.

6d. Substitute methylating agents are needed, to replace diazomethane in the existing regulatory enforcement methods for propiconazole on plant and animal commodities. This deficiency will be resolved in reregistration.

6e. The metabolism of propiconazole in animals is adequately understood. The residues of concern are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid (M. Rodriguez, 2/25/93).

6f. Analytical Method AG-517, appears adequate for enforcement analysis of propiconazole in animal commodities.

7a. Analytical reference standards for propiconazole and DCBA are available from the U.S. EPA Pesticide and Industrial Chemical Repository in RTP, NC.

7b. Additional analytical reference standards for metabolites of concern identified by new metabolism studies may need to be made available at the Repository in RTP, NC.

8a. The current submission provided no new storage stability data. Maximum lengths of frozen sample storage were: fresh and bulb onions, 14 mos.; carrots, 7.0 mos; and berries, 5.0 months.

8b. Adequate storage stability data were not submitted previously for stone fruit in conjunction with petition 9F3758, but were translated from soybean and peanut storage stability data. Under reregistration, the registrant has agreed to submit new storge stability data for peaches, bananas, wheat grain and celery.

8c. Storage stability data on a root crop, e.g., carrots, will be necessary. Available data and proposed and ongoing storage stability studies can be translated to fresh and dry bulb onions, and whole onion plants, in the interim. If the storage stability study on carrots reflects that residues are not stable, an additional storage stability study on dry bulb onions will also be necessary.

9a. Field trials were initiated prior to the publication of the 1994 Guidelines for conducting Field Trials and are not in compliance with that document. Sampling, however, included the high production states, and the geographic representation of field residue data are adequate, for the purposes of this petition.

9b. Field residue data include the caneberry subgroup (blackberries and raspberries) and bushberries (blueberries), and adequately represent the berry crop grouping.

9c. CBTS tentatively concludes, pending resolution of metabolism and storage stability concerns, that residues of propiconazole are not likely to exceed the proposed tolerances for the subject uses.

10. There are no CODEX, Canadian or Mexican limits for propiconazole on carrots, green or dry bulb onions or the berry crop grouping, therefore there is no compatibility problem at present. We note the U.S. definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), while the CODEX definition is for propiconazole, *per se*, and Mexican definition is for the "presumed" parent. The Canadian definition includes the propiconazole residue defined as parent and metabolites with the 2,4-dichlorophenyl-1-methyl moiety. Due to these differences in definition of the tolerance expression, there may be future harmonization problems with CODEX.

Recommendations

CBTS recommends against the establishment of the proposed permanent propiconazole tolerances. Provided the deficiencies listed in conclusions 2a, 2b, 2c, and 2d are adequately addressed by a revised Section B, CBTS recommends for the establishment of time limited tolerances in/on the following RACs, green onions at 8.0 ppm and dry bulb onions at 0.3 ppm; carrots at 0.2 ppm; and the berry crop grouping at 1.0 ppm, TOX considerations permitting. The time limited tolerance will allow for submission of storage stability, analytical method, and metabolism data, as delineated in conclusions 4a, 4b, 4c, 6b, 6d, 7b, 8b, and 8c.

A DRES run may be conducted using 8.0 ppm for green onions and 0.3 for dry bulb onions, 0.2 ppm for carrots, and 1.0 ppm for the berry crop group.

Detailed Considerations

Product Chemistry

The available product chemistry data satisfy guidelines 61-2 & 63-2, -3, -4, -6, -7, -10, -11, & -12. Guideline 63-13, the test for stability, is an outstanding data gap, because the sensitivity of the a.i. to metal ions must be determined. (K. Dockter, 1/29/96) This deficiency will be resolved in reregistration.

Proposed Use

The table entitled, "Proposed Use Summary" lists directions for propiconazole use on the berry crop group, carrots, green onions and dry bulb onions, for Tilt™/Orbit™ (EPA Reg. Nos. 100-617 & 100-702); and Tilt™ /Orbit™ Gel (EPA Reg. Nos. 100-737); and Tilt™/Orbit™ 45W (EPA Reg. Nos. 100-TIN/TIR). (The propiconazole technical has the EPA Reg. No. 100-618). When propiconazole is mixed with another fungicide registered for use on the subject crops, directions for the other fungicide, crop/sites, use rates, dilution ratios, precautions, and limitations on the tank mix product label are to be observed, in addition to restrictions on the propiconazole label.

PROPOSED LABEL SUMMARY				
CROP*	**DIRECTIONS/COMMENTS**	**TREATMENT SCHEDULE**	**PHI**	**SEASONAL MAXIMUM**
GREEN ONIONS, DRY BULB ONIONS, & ONIONS GROWN FOR SEED	**For Purple Blotch:** Apply 50-100 g ai/A (4-8 fl oz/A of Tilt or Tilt Gel or Tilt 45W) in sufficient water to provide thorough coverage of the plant canopy.	Apply when conditions favor disease. Continue on 7-10 day interval.	14 DAYS-Dry Bulb Onions 0 DAYS-Green Onions	Do not apply more than 200 g AI/A, or 16 fl oz/A Tilt OR Tilt Gel OR Tilt 45W.
	For Purple Blotch & Botrytis Leaf Blight: Apply 25-50 g ai/A (2-4 fl oz/A of Tilt or Tilt Gel or Tilt 45W) in sufficient water to provide thorough coverage of the plant canopy, mixed with another fungicide registered for use on purple blotch & botrytis leaf blight on green onions, dry bulb onions, onions grown for seed.	Apply when conditions favor disease. Continue on 7 day interval. A wetting agent or spreader-sticker may be used.	14-Dry Bulb Onions 0-Green Onions	Do not apply more than 200 g AI/A, or 16 fl oz/A Tilt OR Tilt Gel OR Tilt 45W.
CARROTS	**For Leaf Blight & Powdery Mildew:** Apply 50 g ai/A (4 fl oz/A of Tilt or Tilt Gel or Tilt 45W).	Apply when conditions favor disease. Continue on 7-10 day interval. A spreader-sticker may be used.	14 DAYS	Do not apply more than 200 g AI/A, or 16 fl oz/A Tilt OR Tilt Gel OR Tilt 45W.
	For Leaf Blights: Apply 25 g ai/A (2 fl oz/A of Tilt or Tilt Gel or Tilt 45W) tank mixed with 0.75 ai/A Chlorothalonil.	Apply when conditions favor disease. Continue on 7-10 day interval.	14 DAYS	Do not apply more than 200 g AI/A, or 16 fl oz/A Orbit OR Orbit Gel OR Orbit 45W. **NOTE: See Peanut Section of Propiconazole label for amt. of chlorothalonil in tank mix.?**
BERRIES: Blueberries	**GENERAL:** Apply using aerial or ground equipment. For aerial application, use 5-10 gal/A water; For ground application, use 20-25 gal/A water.		30 DAYS	Do not apply more than 385 g AI/A, or 30 fl oz/A Orbit OR Orbit Gel OR Orbit 45W.
	For mummyberry disease: Apply 77 g ai/A (6 fl oz/A of Orbit or Orbit Gel or Orbit 45W) up to 5 times, as specified on the label.	1)At leaf bud break 2)7-10 days after bud break 3)At Pink Bud 4)7-10 days later, at early bloom 5)Between Full Bloom & Early Petal Fall.	30 DAYS	Do not apply more than 385 g AI/A, or 30 fl oz/A Orbit OR Orbit Gel OR Orbit 45W.
	For Leaf/Stem Spot & Rust: Apply 77 g ai/A (6 fl oz/A of Orbit or Orbit Gel or Orbit 45W) **NOTE: MAX APPLICATION NUMBER (5 TIMES) NOT SPECIFIED ON THE LABEL.**	1-When Conditions favor disease development. Repeat Applications on a 4-Week Spray Interval.	30 DAYS	Apply up to 5X (385 g AI/A, or 30 fl oz/A Orbit OR Orbit Gel OR Orbit 45W).
BERRIES: Blackberry, Elderberry, Huckleberry, Loganberry, Raspberry-Black and Red	**For Leaf & Cane Spot:** Apply 77 g ai/A (6 fl oz/A of Orbit or Orbit Gel or Orbit 45W), up to 5X per season. NOTE: Only 4 application times specified.	1-Delayed Dormant Spray after training in the spring. 2-Late spring. 3-At Bud Break 4-At Flowering	NONE Listed	Apply up to 5X (385 g AI/A, or 30 fl oz/A Orbit OR Orbit Gel OR Orbit 45W).
	For powdery mildew: Apply 77 g ai/A (6 fl oz/A of Orbit or Orbit Gel or Orbit 45W), up to 5X per season.	Apply at 5% to 10% Bloom. Repeat at full bloom & then on 14 day interval, while conditions favor disease.	NONE Listed	Do not apply more than 385 g AI/A, or 30 fl oz/A Orbit OR Orbit Gel OR Orbit 45W.
BERRIES: Currant, Gooseberry	**For Leaf Spot:** Apply 77 g ai/A (6 fl oz/A of Orbit or Orbit Gel or Orbit 45W), up to 5X per season.	1-Apply just after harvest. 2-Repeat Prior to Bloom 3-Apply after petal fall.	30 DAYS	Do not apply more than 385 g AI/A, or 30 fl oz/A Orbit OR Orbit Gel OR Orbit 45W.

*** NOTE: The crop definitions, used by the petitioner, are given on the next page.**

The petitioner's crop definitions for blackberry, green onions, and dry bulb onions are listed in the following chart.

CROP DEFINITIONS (PETITIONER'S)
BLACKBERRY: Bingleberry, black satin berry, boysenberry, Cherokee blackberry, Chesterberry, Cheyenne blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, himalayaberry, hullberry, lavacaberry, lowberry, lucretiberry, mammoth blackberry, Marion Berry, nectarberry, olallieberry, Oregon evergreen berry, phenomenalberry, rangeberry, ravenberry, rossberry, Shawnee blackberry, youngberry.
GREEN ONIONS: Green onions, leeks, spring onions or scallions, Japanese bunching onions, green shallots, or green eschalots.
DRY BULB ONIONS: Garlic, onions (dry bulb), and shallots (dry bulb)

The proposed use directions for carrots state that 50 g ai/A (0.11 lb ai/A) is applied to up to 200 g ai/A (0.44 lb ai/A) per season, but include no volume of water to be used. Similarly, proposed labels for green onions, dry bulb onions and onions grown for seed, specify usage in terms of amount of fl oz (or g ai)/A to be used, with a maximum total of 200 g ai/A (0.44 lb ai/A) per season, with "sufficient water to obtain thorough coverage."

The proposed label for green and dry bulb onions, onions grown for seed, and carrots, states that propiconazole is to be used in "sufficient water to provide sufficient coverage." This label is inadequate and should be modified to specify the minimum volume of water necessary to ensure coverage.

The following restriction should be added to the proposed use directions for carrots, "Do not tank mix with any pesticidal product which does not have a registered use."

A revised Section B is needed stating the amount of propiconazole ai applied expressed as lbs ai/A.

No PHI was included on the proposed label for use of propiconazole on blackberries or raspberries, although all of the field data represent a PHI of 30 days. A PHI of 30 days should be specified on the label.

The label proposes a use on onions grown for seed which is identical to the proposed uses on green and dry bulb onions. Residues resulting from the seed use are expected to be considerably less than those from the direct uses on green and dry bulb onions, therefore, no residue data are needed for onions grown for seed use.

Plant and Animal Metabolism

Nature of Residue - Plants

Previous plant metabolism studies using triazole-labeled propiconazole have shown that soil residues are absorbed by crops planted in rotation with propiconazole treated peanuts, and such residues are translocated throughout the plant and the fruit of the plant. Propiconazole and its metabolites in soil were absorbed and metabolized by peanuts, wheat, and corn. (A. Smith, 4F3007, 5/15/84).

The metabolic route involved the conversion of the parent propiconazole to more polar compounds which were subsequently conjugated with sugars. The major component of the peanut kernel is the triazole ring (about 50% of the activity), 1,2,4-triazole, which is conjugated with the amino acid alanine, to form the conjugate, 1,2,4-triazole-1-alanine. Residues in the mature stalk of peanuts consist of 5 components with the intact parent ring system (i.e., dichlorphenyl, triazole, and dioxaolane rings): the unchanged parent, 1-[[2-(2,4-dichlorphenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole; and 4 hydroxylated derivatives of the parent compound (given the group name CGA-118241), which are also conjugated with sugars. A minor metabolic pathway yields the alkanol metabolite, alpha-(2,4-dichlorophenyl)-1H-1,2,4-triazole-1-ethanol, which is also conjugated with sugars. The hydroxylation is believed to be on the beta carbon of the alkyl chain on the dioxolane ring, and the 4 hydroxylated derivatives represent the cis/trans and D and L isomeric forms. The cis/trans isomers of the gamma hydroxylated derivative, CGA-118242, are probably present at low levels. These components represent 72-79% of the total radioactive activity in the mature peanut plant. (A. Smith, 4F3007, 5/15/84).

Additional plant metabolism data were submitted on corn, winter wheat, and lettuce. The peanut study was inadequate because it did not identify metabolites in nutmeats and shells (triazole or phenyl label). In addition, all metabolism studies should have used material radiolabelled in the dioxolan portion of the molecule, as well as triazole-labeled propiconazole. None of the metabolism data submitted were considered adequate, according to the reregistration document of 10/20/94. The Agency's 9/7/94 reregistration document required that phenyl-^{14}C-propiconazole be applied to wheat, bananas, and pecans, reflecting registered use patterns.

Ciba-Geigy has proposed a new plant metabolism study with phenyl-^{14}C-propiconazole on celery, to supplement metabolism data on peanuts, grapes, corn, winter wheat, and lettuce.

Since we have a single moiety analytical method, we can tentatively conclude that the nature of the residue is

understood, pending receipt of additional metabolism studies.

The metabolism of propiconazole in/on plants and animals is tentatively understood, pending receipt of additional metabolism studies required for reregistration. The residues of concern are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent (PP#8F3674, 12/14/88).

However, the reregistration document of 10/20/94 stated that metabolism data should be provided on all crops for which a field trial has (or will be) done. Root crops are significantly different from other crops, and may demonstrate a different metabolic pathway, therefore, an additional metabolism study is necessary on a tuber crop, i.e., carrots.

Nature of Residue - Animals

No additional animal metabolism data were submitted for this proposed use. The metabolism of propiconazole in/on animals is adequately understood. The residues of concern are propiconazole *per se* and its metabolites determined as 2,4-dichlorobenzoic acid (M. Rodriguez, 2/25/93).

Residues in animals (goats, rats, mice) consist of the parent propiconazole and metabolites containing the intact parent structure with hydroxy groups, carboxylic acid groups, or hydroxy acid groups on the alkyl side chain of the dioxolane rine (CGA-118244, CGA-118245, CGA-121676, alpha-hydroxy-carboxylic acid). These components appear free and as glucuronide and sulfate conjugates. Lesser quantities of residue components consist of the intact dichlorophenyl and triazole-ring structure, i.e., CGA-91304 and CGA-91305. These components may contain hydroxy and methoxy groups on the phenyl ring and appear as free and as glucuronide and sulfate conjugates. Meat (liver) and milk, contain, in addition tc traces of the above components, triazole (CGA-71019), triazolealanine conjugate, and possibly the acetyl derivative of triazolealanine (about 50% of milk residues). In tissues, the triazole ring is conjugated with aminoacids and possibly bound in protein linkages. Residues do not concentrate in the fat of meat or milk (4F3074, A. Smith, 7/12/84).

No animal feed items are associated with use of propiconazole on berries or green onions, dry bulb onions, or onions grown for seed. Secondary residues of propiconazole in meat, milk, poultry, and eggs are not expected to occur as a result of these proposed uses.

Carrot culls are feed items for beef and dairy cattle, and breeding and finishing swine. However, secondary residues in animal commodities are not expected to exceed existing tolerances as a result of the proposed use of propiconazole on carrots.

Analytical Methods/Enforcement Methodology

Analytical methodologies for determination of propiconazole and its metabolites in plant and animal commodities (Ciba-Geigy Analytical Methods AG-454 and AG-517, respectively) have been successfully validated by EPA's Analytical Chemistry Laboratory and are approved for publication in PAM II (letter by S. Malak to A. Marcotte, FDA, 5/28/87)(copies may be obtained from PRPRB/FOD).

Recovery of propiconazole via FDA Multiresidue Protocol D (PAM II 232.4) is complete while recovery of propiconazole metabolites (CGA 91305, CGA 118244 and 1,2,4-triazole) via this method is variable (Pestrak data base (11/6/90)).

The current enforcement method for plants is a single moiety analytical method which detects residues as 2,4-dichlorobenzoic acid methyl ester and reports them as propiconazole equivalents. Ciba-Geigy's Analytical Method AG-454 has been validated by EPA's Analytical Chemistry Laboratory. Pending publication in PAM II, the analytical method is available from PRPRB/FOD.

If the new metabolism studies identify metabolites which are not adequately detected by the current regulatory enforcement method, a revised method will be necessary, which measures all of the relevant metabolites. In addition, independent laboratory and petition method validation (ILV and PMV) will be needed for the new method.

CBTS tentatively concludes that adequate enforcement methods are available for the proposed tolerances in plant commodities, pending receipt of the new metabolism studies.

If additional relevant plant metabolites are identified, which are not determined by the single moiety method, a new analytical method will be needed to regulate residues of concern, including independent laboratory and petition method validation (ILV and PMV).

Substitute methylating agents are needed, to replace diazomethane in the existing regulatory enforcement method for plants. This deficiency will be resolved in reregistration.

Analytical reference standards for propiconazole and DCBA are available from the U.S. EPA Pesticide and Industrial Chemical Repository in RTP, NC.

Additional analytical reference standards for relevant metabolites identified by new metabolism studies may need to be made available at the Repository in RTP, NC.

Analytical Method AG-517, appears adequate for enforcement and

analysis of propiconazole in animal commodities involving residues containing the 2,4-dichlorobenzene ring in animal tissues, eggs or milk. This method was acceptable for Phase 5 review, however, a substitute methylating agent is needed, to replace diazomethane in the regulatory enforcement method. This deficiency will be resolved in reregistration.

Residue data for the subject petition were determined by Analytical Method AG-454B, which is essentially AG-454A, the regulatory enforcement method. Samples are extracted by refluxing with 20% concentrated ammonium hydroxide/methanol for one hour. An aliquot is concentrated and refluxed with potassium permanganate in sodium hydroxide to convert propiconazole and its metabolites to the 2,4-dichlorobenzoate salt. After acidification, the dichlorobenzoic acid is partitioned into 10% diethyl ether/hexane and the organic phase taken to dryness. The acid is converted to the methyl ester with diazomethane and the methyl ester quantitated by capillary gas chromatography/electron capture detection. The residue detected is 2,4-dichlorobenzoic acid methyl ester and reported as propiconazole equivalents using the factor 1.79.

The current submission determined recoveries for the various crops, using fortified control samples. (All the blank controls were <0.05 ppm propiconazole.) Recoveries varied by crop and are summarized below. The limit of quantification is 0.05 ppm.

FORTIFICATION RESULTS

CROP	SAMPLE TESTED	FORTIFICATION LEVEL (ppm)	RECOVERY RANGE, %	MEAN RECOVERY (%)	NO. SAMPLES
GREEN & BULB ONIONS	WHOLE PLANT	0.05-3.0	66-142	96.9	14
	BULB, FRESH	0.05-0.20	70-135	98.8	14
	DRY BULB	0.05-0.20	80-140	111	14
	DRY FLAKES	0.05-1.00	104-133	118	2
CARROTS	ROOTS	0.05	79-85	82.1	7
		0.50	72-81	77.4	7
BERRIES	BLUEBERRIES	0.05,0.50,1.00	70-92	80.9	10
	BLACKBERRIES	0.05,0.50	69-85	78.3	3
	RASPBERRIES	0.05,1.00	84-93	88.5	2

Storage Stability

Storage stability studies have been conducted in fortified soybean fodder and grain which was fortified to a level of 0.4 ppm propiconazole, analyzed, and stored at 5 F (-15 C) for 6 months. An average of 82-89% of initial propiconazole residues were recovered after 6 months. (PP#4F3007, A. Smith, 5/15/84). Further analyses showed that levels of propiconazole recovered at 6 months were 75% of the original in soybean fodder and 62% of the original level in soybean grain. These studies adequately demonstrated that propiconazole residues in soybean fodder and grain were stable for 4 - 6 months. (PP#8F3654, M. Flood, 11/8/93).

In a second storage stability study, field weathered peanut fodder, shells, and nutmeat (having initial residues of 7.6-13 ppm, 1.3-7.7 ppm, and 0.15-0.67 ppm propiconazole, respectively) were stored for 25 months at 5 F (-15 C). After 25 months of frozen storage, the percentages of initial residues were: 98-146% of peanut fodder, 95-147% of peanut shells, and 249-333% of nutmeat. (PP#4F3007, A. Smith, 5/15/84). Storage stability data for peanut fodder, shells and nutmeat were judged inadequate and storage stability was listed as a data gap in the Phase IV Reregistration document of 4/30/92.

The current submission provided no new storage stability data. Maximum lengths of frozen storage of samples were: fresh and bulb onions, 14 months; carrots, 7.0 months; and berries, 5.0 months.

Storage stability data used to support previous registration in stone fruits were data on soybean fodder and grain (stable to 4 to 6 months) and peanut fodder, shells, and nutmeats (which were believed to be stable for 25 months, at the time of the petition). No storage stability data on stone fruit or any other fruiting vegetable are available for propiconazole (9F3758).

Ciba-Geigy has agreed, under the 10/20/94 Phase IV Reregistration document, to submit storage stability studies on a stone fruit (peaches), as well as studies on bananas, the cereal grains crop group (corn oil, corn meal, wheat grain), a leafy vegetable (celery), and the legumes crop group (peanut hulls, peanut nutmeat, and peanut hay).

The ongoing storage stability study on a stone fruit, peaches, should suffice for the berry crop grouping, provided it demonstrates sample stability.

Storage stability data on a root crop, e.g., carrots, will be necessary. Available data and proposed and ongoing storage stability studies can be translated to fresh and dry bulb onions, and whole onion plants, in the interim. If the storage stability study on carrots reflects that residues are not stable, an additional storage stability study on dry bulb onions will also be necessary.

Residue Data

Field residue data were submitted for green and dry bulb onions, carrots, and berries, from major crop-producing states. They were initiated prior to the publication of the 1994 Guidelines for conducting field trials and are, therefore, not in compliance with that document. Sampling included the high production states, and the geographic representation of field residue data are adequate, for the purposes of this petition.

Green and Dry Bulb Onions

Residue data for green and dry bulb onions were submitted, from work conducted during 1993 in California, Colorado, Georgia, Idaho, Michigan, Oregon, and Texas, representing 77% of states growing green onions, and 74% of states growing bulb onions.

Onion field samples reflected two foliar applications, 7 days apart, using Tilt 3.6 EC (EPA Reg 100-617, containing 3.6 lb ai/gal) at the 1X and 2X application rates [100 g ai/A (0.22 lb ai/A) and 200 g ai/A (0.44 lb ai/A)]. PHI's of 0 and 14 days were observed. A "X77 penetrator" was used along with the propiconazole, at the 0.25% v/v application rate. Water dilution rates (gallons/Acre) were not specified. Fresh and dry bulb onions were stored frozen (-20 C) for 8 - 14 months, whole onions were stored frozen for 9 - 14 months.

The current maximum proposed application rate for green, dry bulb onions, or onions grown for seed is 200 g ai/A (0.44 lb ai/A) (equivalent to 16 fl oz/A Tilt, Tilt Gel or Tilt 45W per season). The minimum proposed PHI for dry bulb onions is 14 days, and 0 days for green onions.

Field residue data are summarized in the table entitled, "Residue data following use of propiconazole on green/dry bulb onions."

RESIDUE DATA FOLLOWING USE OF PROPICONAZOLE ON GREEN/DRY BULB ONIONS*

TEST LOCATION	SAMPLE TESTED	MONTHS FROZEN	RATE	PHI	PPM PROPICONAZOLE
Texas AT 1X	WHOLE PLANT	14	1X	0 D	2.6,3.2,3.2,4.3
	FRESH BULB	13	1X	14 D	<0.05,<0.05,<0.05,<0.05
	DRY BULB	13	1X	14 D	<0.05,<0.05,<0.05,<0.05
Texas AT 2X	WHOLE PLANT	14	2X	0 D	5.8
	FRESH BULB	13	2X	14 D	<0.05
	DRY BULB	13	2X	14 D	<0.05
Georgia	WHOLE PLANT	14	1X	0 D	2.0,2.5,2.6,4.3
	FRESH BULB	14	1X	14 D	<0.05,<0.05,0.06,0.16
	DRY BULB	14	1X	14 D	<0.05,<0.05,<0.05,0.07
Colorado	WHOLE PLANT	10	1X	0 D	0.57,0.79,0.87,0.89
	FRESH BULB	9	1X	14 D	<0.05,0.05,0.06,0.07
	DRY BULB	9	1X	14 D	<0.05,<0.05,0.08,0.09
California	WHOLE PLANT	11	1X	0 D	3.2,3.9,6.1,7.5
	FRESH BULB	10	1X	14 D	<0.05,0.06,0.07,0.15
	DRY BULB	10	1X	14 D	<0.05,<0.05,0.08,0.17
	DRY FLAKES	10	1X	14 D	<0.05,<0.05,<0.05,0.06
Oregon	WHOLE PLANT	9	1X	0 D	0.78,1.2,1.7,1.9
	FRESH BULB	8	1X	14 D	<0.05,<0.05,<0.05,<0.05
	DRY BULB	8	1X	14 D	<0.05,<0.05,<0.05,<0.05
Idaho	WHOLE PLANT	9	1X	0 D	1.5,1.8,2.1,2.5
	FRESH BULB	8	1X	14 D	0.05,0.06,0.07,0.11
	DRY BULB	9	1X	14 D	<0.05,<0.05,<0.05,0.07
Michigan AT 1X	WHOLE PLANT	10	1X	0 D	1.1,1.2,1.4,2.2
	FRESH BULB	10	1X	14 D	0.13,0.14,0.22,0.23
	DRY BULB	10	1X	14 D	0.08,0.09,0.18,0.18
Michigan AT 2X	WHOLE PLANT	10	2X	0 D	3.3
	FRESH BULB	10	2X	14 D	0.51
	DRY BULB	10	2X	14 D	0.41

OVERALL SUMMARY	SAMPLE TESTED		RATE	PHI	RANGE (PPM)	MEAN	#SMPL
	WHOLE PLANT	-	1X	0 D	0.57 - 7.5	2.42	28
	FRESH BULB	-	1X	14 D	<0.05 - 0.23	0.082	28
	DRY BULB	-	1X	14 D	<0.05 - 0.18	0.071	28
	DRY FLAKES	-	1X	14 D	<0.05 - 0.06	0.052	4

* Data submitted with this petition.

Residue field trial data are adequate to support the use of propiconazole on green and dry bulb onions. A revised Section B is needed providing specific dilution directions. Nine trials were conducted in seven states within the major region where onions are grown. The residue data for green onions and dry bulb onions indicate that residue levels are not likely to exceed 8.0 ppm green onions and 0.3 ppm for dry bulb onions, when propiconazole is used as directed (minimum 0 day PHI for green onions, minimum 14 day PHI for dry bulb onions, and maximum of 200 g ai/A per season for both green and dry bulb onions).

Carrots

Field residue data for carrots were conducted during 1994 to 1995 in Washington, Texas, Ohio, Florida, New York, Michigan, and California, representing 90% of U.S. carrot production. Carrot field samples reflected four foliar applications of Tilt 3.6 EC, (contains 3.6 lb ai/gal) at the 1X and 2X application rates (50 g

ai/A and 100 g ai/A). A 1% v/v spreader /sticker and a minimum of 25 gal water/acre was used for dilution but an unspecified treatment interval was used. PHI's of 13 and 14 days were observed. NOTE: The current maximum proposed application rate for Tilt/Orbit, Tilt Gel/Orbit Gel, or Tilt 45W/Orbit 45W is 200 g ai/A, with a minimum PHI of 14 days.

Carrots were stored frozen 0.5 to 7.0 months, but no storage stability data were provided for carrots. Storage stability data are needed for carrots. If residues are found to be unstable in carrots, storage stability data will be required for bulb onions, also.

Field residue data are summarized in the following table.

RESIDUE DATA FOLLOWING USE OF PROPICONAZOLE ON CARROTS*

TEST LOCATION	RATE	**PHI (DAYS)**	PPM PROPICONAZOLE
WASHINGTON	1X	14	<0.05,<0.05
TEXAS	1X	14	0.06, 0.08
TEXAS	2X	14	0.10
OHIO	1X	13	0.14,0.17
FLORIDA	1X	14	0.12,0.12
FLORIDA	2X	14	0.17
NEW YORK	1X	14	0.10,0.14
MICHIGAN	1X	14	0.10,0.16
CALIFORNIA	1X	14	<0.05,0.07
CALIFORNIA	2X	14	0.11
OVERALL SUMMARY	**RATE**	**PHI (DAYS)**	**RANGE (PPM) MEAN #SMPL**
7 STATES	1X	13-14	<0.05-0.17 0.10 12
LISTED ABOVE	2X	14	0.10-0.17 0.13 3

* Data submitted with this petition.

Residue field trial data are adequate to support the use of propiconazole on carrots, providing an adequate Section B is submitted, providing specific dilution directions. Ten trials were conducted in seven states within the major region where carrots are grown. The residue data for carrots indicate that residue levels are not likely to exceed 0.2 ppm on carrots, when propiconazole is used as directed (minimum 14 day PHI and maximum of 200 g ai/A Tilt or Orbit, Tilt or Orbit Gel or Tilt 45W or Orbit 45W per season).

Berries

Field residue data for blueberries, blackberries and raspberries were submitted, from work conducted during 1994 in Maine, Michigan, New Jersey, North Carolina, Oregon, and Washington. The sampling represented the following percentages of U.S. berry

production, blueberries-77%, blackberries- 68%, and raspberries-27%. A berry crop grouping tolerance requires data on a caneberry (blackberries and raspberries) and bushberries (blueberries). The samples provided sufficiently represent the berry crop grouping.

Berry field samples reflected either 5 foliar applications at 77 g ai/A (1X) or 154.0 g ai/A (2X) of Tilt 3.6 EC, with NO application interval specified, using Tilt 3.6 EC (EPA Reg 100-617, containing 3.6 lb ai/gal). A 1% v/v spreader/sticker and a minimum of 20 gal water/acre was used for dilution. PHI's of 30 days were observed for the testing. NOTE: The current maximum proposed application rate is up to 5 applications or 385 g ai/A per season, with a minimum PHI of 30 days for blueberries and gooseberry currants. No PHI was proposed for use of propiconazole on blackberries or raspberries, although all of the field data represent a PHI of 30 days. A PHI of 30 days should be specified on the label.

Berries were stored frozen at -20 C for 2.5 - 5.0 months.

Field residue data are summarized in the table, "Residue data following use of propiconazole on berries"

RESIDUE DATA FOLLOWING USE OF PROPICONAZOLE ON BERRIES*

TEST LOCATION	RATE	PHI (DAYS)	PPM PROPICONAZOLE
MAINE	1X	30	0.36,0.53
MICHIGAN	1X	30	0.22,0.25
MICHIGAN	2X	30	0.40
NEW JERSEY	1X	30	0.36,0.45
NEW JERSEY	2X	30	0.98
NORTH CAROLINA	1X	30	0.66,0.57
OREGON	1X	30	0.28,0.34
OREGON	2X	30	0.27,0.31
WASHINGTON	1X	30	0.14,0.18
OVERALL SUMMARY	**RATE**	**PHI (DAYS)**	**RANGE (PPM) MEAN #SMPL**
6 STATES LISTED ABOVE	1X 2X	30 30	0.14-0.66 0.35 14 0.40-0.98 0.69 2

* Data submitted with this petition.

Residue field trial data are adequate to support the use of propiconazole on berries, providing an adequate Proposed Use Section and the proposed labels are submitted, providing specific dilution directions and a 30 day PHI for blackberries and raspberries. Trials were conducted in six states in the major regions where berries are grown. The residue data for berries

indicate that residue levels are not likely to exceed 1.0 ppm on the berry crop grouping, when propiconazole is used, as directed, (minimum 30 day PHI and maximum of 385 g ai/A Tilt or Orbit, Tilt or Orbit Gel or Tilt 45W or Orbit 45W, per season).

Secondary Residues in Meat and Milk

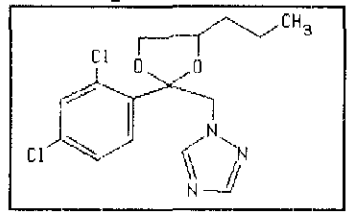
Since there are no significant animal feed items involved with onions or berries, there are no concerns over secondary residues of propiconazole in livestock or poultry, meat byproducts, fat, milkfat, whole milk, or eggs, resulting from use of propiconazole on these crops.

Carrot culls are a significant animal feed item, comprising up to 40% and 25% of the diet of dairy and beef cattle, respectively, and 20% and 10% of the breeding and finishing swine diet, respectively. However, existing tolerances on animal commodities are not likely to be exceeded as a result of the proposed use of propiconazole on carrots.

Other Considerations

There are no CODEX, Canadian or Mexican limits for propiconazole on carrots, green or dry bulb onions or the berry crop grouping, therefore there is no compatibility problem at present. We note the U.S. definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), while the CODEX definition is for propiconazole, *per se*, and Mexican definition is for the "presumed" parent. The Canadian definition includes the propiconazole residue defined as parent and metabolites with the 2,4-dichlorophenyl-1-methyl moiety. Due to these differences in definition of the tolerance expression, there may be future harmonization problems with CODEX.

Propiconazole



ATTACHMENT: International Residue Limit Status Sheet
cc: Kathryn Scanlon (RD-7505C), RF, PP No. 9F3740, L. Kutney, E. Haeberer, Circ, Beth Doyle
CM2:305-5351:RM816G:7509C:LLKutney:llk-6/9/96
RDI: E. Haeberer, 6/10/96; R. Loranger: 6/12/96

13544

R139172

Chemical: Propiconazole

PC Code:
122101
HED File Code: 11500 Petition Files Chemistry
Memo Date: 6/14/1996
File ID: DPD219664
Accession #: 000-00-0117

HED Records Reference Center
2/7/2007