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

APR 8 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: *PP9F3758: Propiconazole (Tilt, Orbit) in Wild Rice, Apricots, Nectarines, Peaches, Plums, and Prunes. Amendment of October 8, 1992.*
CBTS #10742
DP Barcode #D183633
EPA Reg. No.'s 100-618, 100-617, 100-702
MRID #425114-01

FROM: María Isabel Rodríguez, Chemist
Tolerance Petition Section III
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

María Isabel Rodríguez
April 8, 1993.

THROUGH: Philip V. Errico, Section Head
Tolerance Petition Section III
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Philip V. Errico

TO: Susan Lewis/Sidney Jackson
Product Manager Team #21
Registration Division (H7505C)

Ciba-Geigy Corporation, Agricultural Division, submitted a letter dated October 8, 1992 from Dr. Eileen D. King-Watson, Regulatory Manager. The package contains revised Sections B and F for tolerances of propiconazole in wild rice and stone fruits, revised product labeling, and submission of aerial residue data for wild rice. All these apply to Propiconazole Technical (EPA Reg. No. 100-618), Tilt® Fungicide (EPA Reg. No. 100-617), and Orbit™ Fungicide (EPA Reg. No. 100-702). This is a response to DEB (now CBTS) Review #'s 5226 to 5228 (S. Malak, November 28, 1989, PP9F3758, MRID #'s 410638 to 410638-03). At that time the registrant proposed to amend 40 CFR §180.434 by the establishment of tolerances on wild rice (in Minnesota) at 0.5 ppm and a crop group tolerance for stone fruit at 1.0 ppm.

Conclusions and Recommendations:

All the deficiencies listed in the DEB (now CBTS) Review #'s 5226 to 5228 (S. Malak, November 28, 1989, PP9F3758, MRID #'s 410638 to 410638-03) have been resolved. Therefore, toxicological considerations permitting, and with a revised Confidential of Statement of Formula as discussed under Additional Comments (below), CBTS has no objections to the establishment of food tolerances for the residues of the fungicide propiconazole (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 and expressed as parent compound equivalents in or on wild rice for use in Minnesota only (regional tolerance) at 0.5 ppm and for use in/on apricots, nectarines, peaches, plums, and fresh prunes at 1.0 ppm.

Discussion:

In the DEB (now CBTS) Review #'s 5226 to 5228 (S. Malak, November 28, 1989, PP9F3758, MRID #'s 410638 to 410638-03) the registrant was asked to submit additional information. The registrant's comments to those questions/requests, as well as CBTS's response to their comments, follow.

1. a. DEB #'s 5226 to 5228, Conclusion #4:

"A revised Section B is needed restricting the use of water drained from treated fields to irrigate other crops. Alternatively, residue data must be submitted from crops irrigated with drained water from Tilt-treated wild rice fields."

b. Registrant's Comments:

Section B of the petition has been revised to prohibit the use of water drained from wild rice fields to irrigate other crops. The change is also reflected in the supplemental label.

c. CBTS's Comments:

The deficiency is considered to be resolved.

2. a. DEB #'s 5226 to 5228, Conclusion #5a:

"Residue data representing aerial applications are needed from Minnesota since, due to the cultural practices of wild rice, use is expected to be solely with aerial equipment."

b. Registrant's Comments:

Three aerial residue trials were conducted using a minimum spray volume of 6 gals/Acre. A minimum spray volume requirement of 5 gals/Acre was placed in the proposed label.

c. CBTS's Comments:

Maximum total residue for aerial application was 0.37 ppm at a pre-harvest interval (PHI) of 28 days, which supports the proposed 0.5 ppm tolerance in wild rice. The deficiency is considered to be resolved (See Residue Data Section below for details).

3. a. DEB #'s 5226 to 5228, Conclusion #5b:

"For national use of Tilt on wild rice, field residue data must be submitted from California, preferably ground and aerial residue data. Alternatively, the petitioner can submit a revised Section F proposing amending 40 CFR §180.434 to include 'Tolerance with regional registration,' in a separate subsection, for wild rice restricting use to Minnesota only."

b. Registrant's Comments:

Section F of the petition has been revised to request a regional registration for propiconazole in wild rice to support the use of propiconazole in Minnesota only.

c. CBTS's Comments:

The deficiency is considered to be resolved.

4. a. DEB #'s 5226 to 5228, Conclusion #6b:

"For a crop group tolerance in/on stone fruit in accordance with 40 CFR §180.34 (f)(9)(xii), additional residue data are needed on sour or sweet cherry. Alternatively, we can conclude that the available residue data are adequate to support the proposed 1.0 ppm tolerance for apricots, nectarines, peaches, plums, and prunes. A revised Section F is needed proposing 1.0 ppm tolerance for residues of propiconazole in/on apricots, nectarines, peaches, plums, and fresh prunes."

b. Registrant's Comments:

Section F of the petition has been revised to request tolerances in apricots, nectarines, peaches, plums, and prunes rather than a crop grouping tolerance for stone fruit. The supplemental label for the end use product and the revised Section B also reflect the revision (See Proposed Use Section below for details). A prohibition against use on cherries has been added to the petition and the label.

c. CBTS's Comments:

The deficiency is considered to be resolved.

Additional Comments:

Propiconazole has two optically active carbons and possible cis/trans configurations. The registrant should identify the active isomer(s) and, if

necessary, provide a revised Confidential Statement of Formula listing the active isomer(s) separate from the inactive isomer(s). They should also provide a chemical name which illustrates the stereo configuration of their compound. The R,S or Cahn-Ingold-Prelog convention can be used.

BACKGROUND:

Propiconazole is a systemic ergosterol-biosynthesis-inhibiting fungicide. Tolerances and interim tolerances are established according to 40 CFR §180.434 for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on various raw agricultural commodities.

Propiconazole is a List "C" chemical for which a Registration Eligibility Document has not been issued.

As of February 24, 1993, the CBTS recommended favorably for a Section 18 (93-MN-002, M.I. Rodríguez) on the use of propiconazole in wild rice in the state of Minnesota.

DETAILED CONSIDERATIONS:

Proposed Use:

Tilt® Fungicide: For use in wild rice in Minnesota only. For control of Helminthosporium leaf blight, apply 6 fl. oz./Acre at both booting and heading, or make a single application of 8 fl. oz./Acre at booting. For aerial applications, apply in a spray volume of 5-10 gals./Acre. Do not use water drained from treated fields to irrigate other crops.

Orbit™ Fungicide: For use on apricots, nectarines, peaches, plums, and prunes.

a. For use on apricots, nectarines, peaches, and plums (East of the Rocky Mountains): Do not apply to cherries or prunes. For aerial applications a minimum spray volume of 5-10 gals./A is recommended. For ground applications a minimum spray volume of 50 gals./A is recommended.

b. For use on apricots, nectarines, peaches, and plums (West of the Rocky Mountains): Do not apply to cherries. For aerial applications a minimum spray volume of 20 gals./A is recommended.1 For ground applications a minimum spray volume of 50 gals./A is recommended.

c. For use on prunes (West of the Rocky Mountains): Do not apply to cherries. For aerial applications a minimum spray volume of 20 gals./A is recommended. For ground applications a minimum spray volume of 50 gals./A is recommended.

For all the uses of Orbit, it is more effective when applied before a

rainfall and allowed to dry.

The proposed use was adequately described in the submitted petition.

Residue Data - Magnitude of the Residue in Plants:

Smith, J.W. December 19, 1991 Propiconazole: Response to EPA Review of Propiconazole (Tilt 3.6E) on Wild Rice Including Results of Additional Field Trials. Study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC. Lab Project ID #ABR-90091. (MRID #425114-01)

The purpose of the study was to provide residue data following aerial application of propiconazole to wild rice in Minnesota.

Data from three field trials in Minnesota using a foliar spray treatment of Tilt 3.6E at a maximum use rate of a single application of 8 fl oz (100 g ai/Acre) at booting, or two applications of 6 fl oz (75 g ai/Acre) each at booting and heading, or two 6 fl oz (75 g ai/Acre) postemergence applications at booting and heading were performed. An exaggerated 2X rate was also performed at 200 g ai/A and 150 + 150 g ai/A for comparison purposes. Residue data for ground application were presented as supplemental information for comparison.

The wild rice was grown under normal agricultural conditions to maturity. Samples were collected at random. They were not trimmed, cleaned, or washed. After collection, wild rice straw and grain samples were stored frozen at approximately -20 °C for no more than 14 months until analysis.

Propiconazole residues were determined as 2,4-dichlorobenzoic acid (DCBA) methyl ester and converted to propiconazole equivalents for wild rice straw and grain. Only residues for the grain are reported in the tables in this review.

Maximum total residue for aerial application was 0.37 ppm at a PHI of 28 days. For ground application, the maximum total residue was 0.40 ppm at a PHI of 27 days.

Representative chromatograms were included for review.

Propiconazole Residues in Wild Rice Grain

Field Test	Application Rate (Grams ai/Acre)	PHI (Days)	Residue (ppm)
MW-FR-707-89	Control	--	<0.05
	100 (1X)	50	<0.05
	100 (1X)	50	<0.50
	200 (2X)	50	<0.05
	200 (2X)	50	<0.05
	75 + 75 (1X)	42	0.15
	75 + 75 (1X)	42	0.10
	150 + 150 (2X)	42	0.18
	150 + 150 (2X)	42	0.19
	75 + 75 (Aerial)	43	0.09
	75 + 75 (Aerial)	43	0.09

Field Test	Application Rate (Grams ai/Acre)	PHI (Days)	Residue (ppm)
MW-FR-708-89	Control	--	<0.05
	100 (1X)	41	<0.05
	100 (1X)	41	<0.05
	75 + 75 (1X)	34	0.08
	75 + 75 (1X)	34	0.09
	75 + 75 (Aerial)	35	0.10
	75 + 75 (Aerial)	35	0.07

Field Test	Application Rate (Grams ai/Acre)	PHI (Days)	Residue (ppm)
MW-FR-709-89	Control	--	<0.05
	100 (1X)	35	0.10
	100 (1X)	35	0.08
	75 + 75 (1X)	27	0.40
	75 + 75 (1X)	27	0.37
	75 + 75 (Aerial)	28	0.37
	75 + 75 (Aerial)	28	0.35

Analytical Methodology:

Samples were analyzed by Method AG-454B, which has been discussed in the previous review as AG-454A. The limit of determination is 0.05 ppm expressed as propiconazole equivalents. For fortifications ranging from 0.05 ppm to 4.0 ppm, the average recovery and standard deviation for fortified substrate samples were 79.0 ± 10.5% (n=8).

cc: MIRodríguez, PP#9F3758, Circulation, Reading File, BAES/HED.

RDI: P. V. Errico (4-7-1993), R. A. Loranger (4-7-1993)
M. I. Rodríguez: Draft (3-29-1993), Edited (4-7-1993)
H7509C/CBTS/CM#2, Room 804-T, Tel #703-305-6710

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9E3758 File

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

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

NOV 2 8 1989

MEMORANDUM

SUBJECT: **PP#9F3758 & Reg. Nos. 100-617 & 100-702. Propiconazole (Tilt) in or on Wild Rice and Stone Fruit. Evaluation of Residue Data and Analytical Methods. MRID #'s 410638-00 to 410638-03, DEB #'s 5226 to 5228.**

FROM: Sami Malak, Ph.D., Chemist
Tolerance Petition Section III
Dietary Exposure Branch (DEB)
Health Effects Division (HED)/H7509C

TO: Susan Torregroas Lewis, PM #21
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch
Insecticides, Rodenticides Support
Health Effects Division (H7509C)

THRU: P. V. Errico, Section Head
Tolerance Petition Section III
Dietary Exposure Branch
Health Effect Division (H7509C)

Ciba-Geigy Corporation, Agricultural Division, proposes to amend 40CFR§180.434 by establishing a regulation to permit the residues of the fungicide, propiconazole (Tilt), 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 and expressed as parent compound equivalents in or on wild rice for use in Minnesota at 0.5 ppm and a crop group tolerance of 1.0 ppm in or on stone fruit.

Tolerances are currently established under 40CFR§180.434 for residues of the fungicide, propiconazole (Tilt), 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 and expressed as parent compound equivalents in or on several raw agricultural commodities at 0.05 to 3.00 ppm, including 0.1 ppm for rice grain, 3 ppm for rice straw, 0.1 ppm for the meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, poultry, and sheep, 0.2 ppm for the liver and kidney of cattle, goats, hogs, horses, poultry, and sheep, 0.1 ppm for eggs, and 0.05 ppm for milk.

A Registration Standard for propiconazole has not been issued.

Conclusions

1(a). The nature of residues in plants is adequately delineated. The residues of concern are the parent fungicide, propiconazole (Tilt), 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 and expressed as parent compound equivalents.

1(b). DEB has not reached a conclusion as to the nature of propiconazole residues in animals. Additional metabolism study in lactating cow using phenyl labelled ^{14}C-propiconazole, has been requested in connection with PP#'s 8F3654 and 8F3674. Since no feed items are involved in this petition, we are not concerned with secondary residues in animal commodities.

2(a). We conclude that adequate analytical methods are available for enforcement of the proposed tolerance of 0.5 ppm for residues of propiconazole in/on wild rice grown in Minnesota. Method AG-454A, which was submitted to the FDA for publication in PAM II, is the acceptable enforcement method.

2(b). A multiresidue detection test method has been previously reviewed and accepted.

3. The storage stability studies propiconazole in wild rice and stone fruit are adequate. Propiconazole is stable in frozen wild rice grain and stone fruit for a period of up to 25 months.

4. A revised Section B is needed restricting the use of water drained from treated fields to irrigate other crops. Alternatively, residue data must be submitted from crops irrigated with drained water from Tilt-treated wild rice fields.

5(a). Residue data representing aerial applications are needed from Minnesota since, due to the cultural practices of

wild rice, use is expected to be solely with aerial equipment.

5(b). For national use of Tilt on wild rice, field residue data must be submitted from California, preferably ground and aerial resiude data. Alternatively, the petitioner can submit a revised Section F proposing amending 40CFR§180.434 to include "Tolerance with regional registration", in a separate subsection, for Wild rice restricting use to Minnesota only.

6(a). With a regional registration restricted to Minnesota only, a final conclusion on the appropriateness of the proposed 0.5 ppm tolerance for residues of propiconazole in/on wild rice awaits submitting the requested additional residue data from Minnesota in which aerial equipment is used [see Conclusion 5(a)].

6(b). For a crop group tolerance in/on stone fruit in accordance with 40CFRS180.34(f)(9)(xii), additional residue data are needed on sour or sweet cherry.

Alternatively, we can conclude that the available residue data are adequate to support the proposed 1.0 ppm tolerance for apricots, nectarines, peaches, plums, and prunes. A revised Section F is needed proposing 1.0 ppm tolerance for residues of propiconazole in/on apricots, nectarines, peaches, plums, and prunes.

7. No feed items are involved in this petition. Therefore, we have no concern for secondary residues in meat, milk, poultry, and eggs for the proposed use.

8. An International Residue Limit Sheet is appended to this review (Attachment 1). There are no Mexican or Canadian tolerances/limits currently established for residues of propiconazole in wild rice or stone fruit. A codex limit of 1 ppm is currently established for residues of propiconazole, per se in/on stone fruit. No Codex tolerances are currently established for residues of propiconazole in wild rice. The methodology used to establish the Codex residue limit determines propiconazole, per se, whereas the US enforcement method determines parent and metabolites as 2,4-dichlorobenzoic acid and expressed as parent. No US data is available to assess the indicator compound approach.

Recommendations

A favorable recommendation for the proposed tolerances in this petition awaits resolution, by the petitioner, of Conclusions 4, 5(a), 5(b), and 6(b).

Detailed Considerations

Manufacturing Process

The manufacturing processes of propiconazole has been adequately discussed in connection with PP#1G2530 (J. Worthington, 1/7/82) and PP#4F3007 (A Smith, 5/15/84). DEB has previously concluded that no residue problems are expected from the impurities.

Formulations

The formulation proposed for use on wild rice is Tilt 3.6E containing 41.8% propiconazole, equals to 3.6 lbs act/gallon, and 58.2% inerts (Reg. No. 100-617). Tilt is formulated from a technical grade active ingredient containing 88% propiconazole. The formulation proposed for use on stone fruit is Orbit 3.6E, currently registered for use on pecans (Reg. No. 100-702). Orbit 3.6 is identical to Tilt 3.6E except for the differences in the trade name. Clearance of the inerts in pesticide formulations is the purview of the Registration Division.

Proposed Use

Wild Rice - Minnesota Only: For disease control of wild rice in Minnesota, the proposed use would allow one or two ground or aerial applications of Tilt 3.6E using 6 fl oz/A/application (75 g ai/A or 0.168 lb ai/A), once at booting and again at heading, or 8 fl oz/A/application (100 g ai/A or 0.225 lb ai/A), at booting only.

Rice residue data was also submitted in this petition. The currently registered use of propiconazole on rice would allow two aerial applications of Tilt 3.6E at the same rate as that proposed in this petition on wild rice (6 fl oz/A/application, equals to 75 gm ai/A). However, applications are not permitted after the boot split and head emergence.

A revised Section B is needed restricting the use of water drained from treated fields to irrigate other crops. Alternatively, residue data must be submitted from crops irrigated with drained water from Tilt-treated wild rice fields.

Stone Fruit - East of the Rocky Mountains (apricots, peaches, nectarine, and Japanese plums): (a) For control of brown rot blossom blight of stone fruit, the proposed use would allow up to 3 applications of Orbit 3.6E using 4 fl oz/A/application (50 g ai/A or 0.11 lb ai/A), in a minimum of 5-10 gallons of water by air or in sufficient water for thorough and uniform coverage of the fruit by ground equipment. The first

application can be made at early bloom, and a second at 50-75% bloom, and a third at petal fall. (b) For control of fruit brown rot of stone fruit, Orbit 3.6 can be applied as needed using 4 fl oz/ A/application (50 g ai/A or 0.11 lb ai/A), beginning 3 weeks before harvest to the day of harvest.

The proposed use prohibits application of Orbit 3.6E to cherries and prunes grown East of the Rocky Mountains.

- West of the Rocky Mountains (apricots, peaches, nectarine, and plums): (a) For control of brown rot blossom blight of stone fruit, the proposed use would allow two applications of Orbit 3.6E using 4 fl oz/A/application (50 g ai/A or 0.11 lb ai/A), in a minimum of 5-10 gallons of water by air or in sufficient water for thorough and uniform coverage of the fruit by ground equipment. The first application can be made at 5-10% bloom and a second at 80-100% bloom. (b) For control of fruit brown rot of stone fruit, Orbit 3.6E can be applied twice at 4 fl oz/A/application (50 g ai/A or 0.11 lb ai/A), beginning 3 weeks before harvest to the day of harvest. (c) For control of brown rot blossom blight of prunes, the proposed use would allow up to 3 applications of Orbit 3.6E using 4 fl oz/A/application (50 g ai/A or 0.11 lb ai/A), in a minimum of 5-10 gallons of water by air or in sufficient water for thorough and uniform coverage of the fruit by ground equipment. The first application can be made at early bloom, and a second at 50-75% bloom, and a third at petal fall. The proposed label prohibits application of Orbit 3.6E to cherries grown west of the Rocky Mountains.

Nature of Residues

Plants - No new plant metabolism studies were submitted with this petition.

The nature of residues of propiconazole in wheat, peanuts, and grapes has been adequately discussed in connection with PP#4F3007 (A. Smith, 5/15/84). Several metabolites were reported as resulting from beta-oxidation of n-propyl side chain, reductive deketalization of dioxolane ring and cleavage of the alkyl bridge between the phenyl and triazole ring systems. The metabolic pathway of propiconazole in plants is appended to this review in Figure 1.

The nature of residues in plants is adequately delineated. The residues of concern are the parent fungicide, propiconazole (Tilt), 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 and expressed as parent compound equivalents.

Animals - No new animal metabolism studies were submitted with

this petition.

The metabolism of propiconazole in the goat and rat has been adequately discussed in connection with PP#4F3007 (A. Smith, 5/15/84). The major metabolites, analogous to the plant metabolism, arise from oxidation of the alkyl side chain, dioxolane ring opening, and cleavage of the alkyl bridge between the phenyl and triazole ring systems.

The metabolic pathway of propiconazole in animals is appended to this review in Figure 2.

DEB has not reached a conclusion as to the nature of propiconazole residues in animals. Additional metabolism study in lactating cow using phenyl labelled ^{14}C-propiconazole, has been requested in connection with PP#'s 8F3654 and 8F3674. Since no feed items are involved in this petition, we are not concerned with secondary residues in animal commodities.

Analytical Method

Residues of propiconazole and metabolites containing the 2,4-dichlorobenzyl moiety were determined by analytical method AG-415 or AG-454A. Method AG-454A, which was submitted for publication in PAM II (S. Malak to Alice Marcotte of FDA, 5/28/87) is the accepted enforcement method. Method AG-415 is an earlier version of Method AG-454A but differs, primarily, from the enforcement method in the oxidation step which converts the parent fungicide and its metabolites containing the 2,4-dichlorobenzyl moiety to 2,4-dichlorobenzoic acid. While a 16-hour reflux with 12N nitric acid is used in method AG-415, the accepted enforcement method utilizes a 1-hour refluxing period with basic potassium permangenate in sodium hydroxide. The change to AG-454A was prompted by the EPA request for a faster enforcement method. The limit of detection of either method is 0.05 ppm.

Representative chromatograms have been provided for the standards, untreated controls, fortified, and treated samples. Method validation was conducted by fortifying wild rice and regular rice samples at 0.1 to 1.0 ppm. Recoveries ranged from 69 to 114%, averaging 92%. At the 0.05 to 0.5 ppm fortification level to various commodities of stone fruit, recoveries ranged from 51 to 142%, averaging 95%.

All control samples of wild rice and stone fruit had no detectable residues (<0.05 ppm).

We conclude that adequate analytical methods are available for enforcement of the proposed tolerance of 0.5 ppm for residues of propiconazole in/on wild rice grown in Minnesota. Method

AG-454A, which was submitted to the FDA for publication in PAM II, is the acceptable enforcement method.

A multiresidue detection test method has been previously reviewed and accepted (PP#'s 4F3074, 4F3007, and 4E3026, S. Malak, 4/28/87).

Storage Stability

In this petition, a storage stability study is reported for propiconazole in wild rice and stone fruit. In the study, treated samples were stored in a freezer for periods of up to 31 months for stone fruit and up to 51 months for wild rice. In either case however, storage stability data are not available beyond 25 months. The data show that degradation of residues in wild rice determined as 2,4-dichlorobenzoic acid is unlikely.

The storage stability studies propiconazole in wild rice and stone fruit are adequate. Propiconazole is stable in frozen wild rice grain and stone fruit for a period of up to 25 months.

Residue Data

Wild rice - Data submitted reflect 5 field trials from Minnesota in which Tilt 3.6 was applied by ground equipment. For comparison between the residues resulting from aerial and ground applications, an additional 5 trials were conducted in Texas in which Tilt 3.6 was applied to regular rice using side-by-side, aerial vs. ground applications. Rice grain samples were taken at normal harvest time, 20-58 days following the last application for wild rice and 38-62 days for regular rice. Samples were frozen (-20°C) until analyzed within 15 months from sampling.

The following are the test results:

Rate/application g ai/A	Maximum Propiconazole Residues in ppm			
	1 application		2 applications	
Wild rice	ground	aerial	ground	aerial
75 (1X)	ND[1/]	----	0.14	----
100 (1.3X)	0.25	----	0.79	----
200 (2.67X)	0.09	----	1.3	----
Rice				
75	----	----	0.17[2/]	0.15[2/]
100	----	----	----	0.63
200	0.22	ND	----	----

1/ ND = non-detectable (<0.05 ppm)

2/ We note that because Tilt was applied to rice after the boot stage (use is allowed before the boot stage), residue values in the grain are higher than the established 0.1 ppm for rice grain.

The 1987 Minnesota Agriculture Statistics and University of California Cooperative Extension Service lists Minnesota and California as two major wild rice growing states producing about equal amounts.

The comparability data between aerial versus ground applications are insufficient to allow a conclusion as to the magnitude of residues in wild rice treated using aerial equipment.

No residue data were submitted from Minnesota in which aerial equipment were used on wild rice. These data are needed since, due to the cultural practices of wild rice, use is expected to be solely with aerial equipment. According to E. A. Oelke, et al (1982) "Wild Rice Production in Minnesota, University of Minnesota, Agricultural Extension Service, Extension Bulletin 464, 38 pp"; wild rice fileds should be flooded with 6-14 inches from germination to 3-4 weeks before harvest. Therefore, ground applications seems to be impractical.

Due to the differences in climate conditions and cultural practices (yields are twice as high in California), field residue data are also needed from California, preferably ground and aerial resiude data. Alternatively, the petitioner can submit a revised Section F proposing amending 40CFR§180.434 to include "Tolerance with regional registration", in a separate subsection, for Wild rice restricting use to Minnesota only.

With a regional registration restricted to Minnesota only, a final conclusion on the appropriateness of the proposed 0.5 ppm tolerance for residues of propiconazole in/on wild rice awaits submitting the requested additional residue data from Minnesota in which aerial equipment is used.

No residue data on the possible byproducts of wild rice, hulls, glumes and debris, as well as straw were submitted. A teleconference with Dr. Jim Percich, a wild rice specialist with the University of Minnesota, indicated that wild rice straw is turned under in the soil, and because of the high silicone content of the hulls and glumes, they are not palatable for animal consumption. These two commodities along with wild rice debris are burned [(612)625-6240]. Accordingly, no additional data on these commodities are needed.

Stone fruit

Data submitted reflect 21 field trials from the major stone fruit growing areas of the US (CA, GA, MI, PA, NY, VA, and WA). In these tests, Orbit 3.6E was applied 3-5 times by air or ground using 50 or 100 g ai/A/application (1 or 2X, respectively). Fresh samples of apricots, nectarines, peaches, and plums were taken at various harvest intervals of 0, 3, and 7 days after the last application. Fresh and dried prunes were taken at normal harvest, 120 days after last application. All samples were then frozen (-20°C) for 6 to 31 months until analyzed. Test results show that residue values ranged from non-detectable (<0.05 ppm) to a maximum level as indicated below:

Fruit	Maximum Residues in ppm at PHI's					
	1X			2X		
	0-day	3-day	7-day	0-day	3-day	7-day
Apricots	0.49	0.83	0.4	0.56	0.38	0.31
Nectarines	0.54	0.67	0.62	0.32	0.12	0.11
Peaches	0.78	0.97	0.69	0.4	0.21	0.71
Plums	0.58	0.36	0.19	ND[1/]	ND	ND

	120-day			
	fresh	dried	fresh	dried
Prunes	ND	0.07	0.27	ND

1/ ND = non-detectable (<0.05 ppm).

Data summary above show maximum propiconazole residues of 0.78 ppm in/on stone fruit reflecting the proposed use.

No residue data were submitted on cherries. For a crop group tolerance in/on stone fruit in accordance with 40CFRS180. 34(f)(9)(xii), additional residue data are needed on sour or sweet cherry.

Alternatively, we can conclude that the available residue data are adequate to support the proposed 1.0 ppm tolerances for apricots, nectarines, peaches, plums, and prunes. A revised Section F is needed proposing 1.0 ppm tolerance for residues of propiconazole in/on apricots, nectarines, peaches, plums, and prunes.

Meat, Milk, Poultry, and Eggs

No feed items are involved in this petition. Therefore, we have no concern for secondary residues in meat, milk, poultry, and eggs for the proposed use.

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Other Considerations

An International Residue Limit Sheet is appended to this review (Attachment 1). There are no Mexican or Canadian tolerances/limits currently established for residues of propiconazole in wild rice or stone fruit. A codex limit of 1 ppm is currently established for residues of propiconazole, per se in/on stone fruit. No Codex tolerances are currently established for residues of propiconazole in wild rice. The methodology used to establish the Codex residue limit determines propiconazole, per se, whereas the US enforcement method determines parent and metabolites as 2,4-dichlorobenzoic acid and expressed as parent. No US data is available to assess the indicator compound approach.

Attachment 1: Codex Sheet (one page).

cc: S. Malak, PP#9F3758 & Reg. Nos. 100-617 & 100-702 (for propiconazole or Tilt). RS File, propiconazole SF, E. Eldredge (ISB/PMSD), RF, and Circulation.

RDI: P. V. Errico: 11/27/89: Richard D. Schmitt: 11/28/89.
H7509C:DEB/HED:CM#2:RM814A:S.Malak:X557-4379:s.m.:11/1/89.

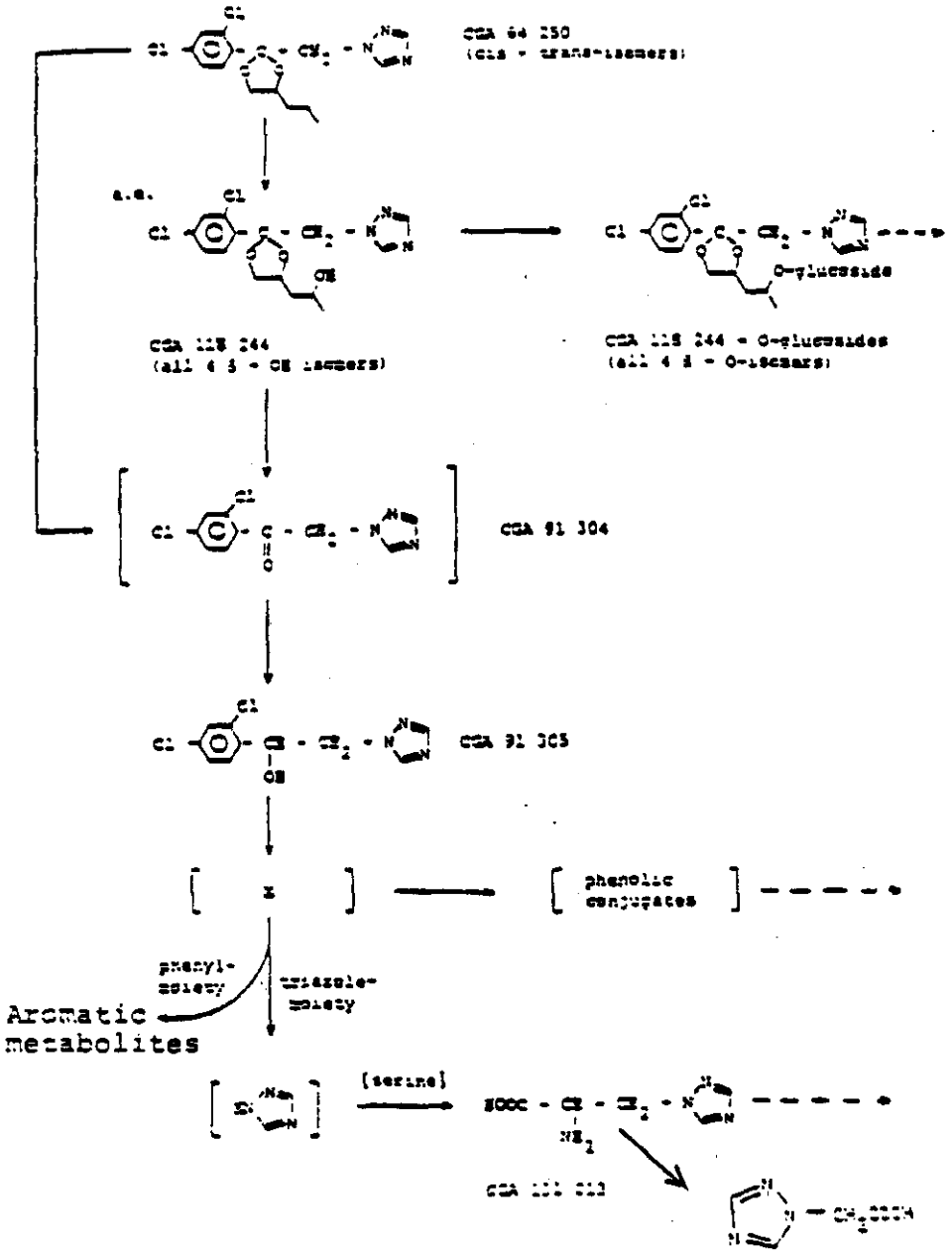

FIGURE 1. PROPOSED PATHWAYS FOR THE METABOLISM OF CGA-6-250 IN PLANTS INCLUDING PECANS

(Reproduced from pp# 4F3007)

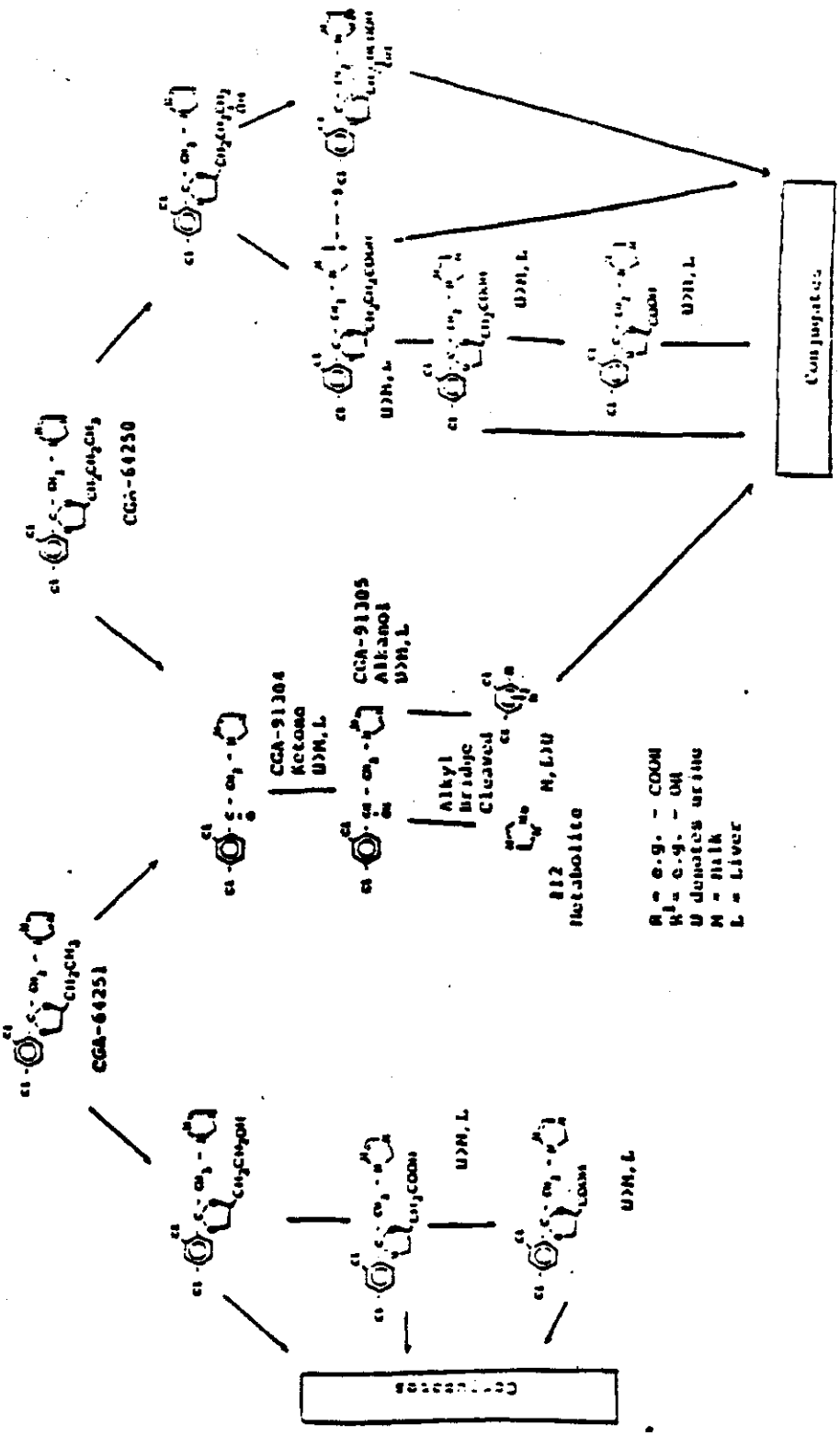

FIGURE 2. PROPOSED METABOLIC PATHWAYS OF CGA-64250 AND CGA-64251 IN GOAT

ABR-83062

(Reproduced from IAM 4F3007)

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Attachment 1

INTERNATIONAL RESIDUE LIMIT STATUS

1/23/97

CHEMICAL Propiconazole (Tilt® or Orbit®)

CODEX NO. 160

CODEX STATUS:

☑ No Codex Proposal Step 6 or above

Residue(if Step 8): propiconazole per se

Crop(s)	Limit (mg/kg)
stone fruit	1

PROPOSED U.S. TOLERANCES:

Petition No. 9F3758

~~BCB~~ OFB Reviewer Sami Malak

Residue: propiconazole and metabolites determined as 2,4-dichlorobenzoic acid

Crop(s)	Limit (mg/kg)
Wild rice, grain	0.5
Stone fruit, group	1.0

CANADIAN LIMITS:

☑ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

END OF DOCUMENT

RECORD OF COMMUNICATION

☐ PHONE CALL ☐ DISCU ON ☐ FIELD TRIP ☐ CONFERENCE
☐ OTHER (SPECIFY)

(Record of item checked above)

TO: Sami Malak
Dietary Exposure Branch
Health Effects Division

FROM: Dr. Jim Percich
University of Minnesota
(612) 625-6240

DATE: 10/19/89

TIME: 11:30 AM

SUBJECT

Wild rice straw and processed commodities are not feed items

SUMMARY OF COMMUNICATION

Contacted Dr. Percich, a wild rice specialist with the University of Minnesota, and asked him about the processing practice of wild rice in Minnesota and whether any of the byproducts is used as feed item. The following is his reply:

(1) Rice straw is left in the field and is plowed under into the soil.

(2) In the milling process, so called polishing, the rac is drawn through heavy wooden rollers operating under high temperature, a process by which rice grain is separated from the hulls, glumes, and debris. Because of the high content of silicone in the hulls and glumes, none of which is palatable for animal consumption, or even for bedding. All these comodities, including debris, are burned.

CONCLUSIONS, ACTION TAKEN OR REQUIRED

The straw of wild rice grown in Minnesota and the processed byproducts, hulls, glumes and debris, are not considered feed items.

INFORMATION COPIES

TO: S. Malak, PP#9E3758, RF, Record of Comm. File, Cultural Practice File (Rice), Circulation

EPA Form 1300-6 (7-72) REPLACES EPA HQ FORM 5300-3 WHICH MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

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1. PP#9E3758

2. Petitioner:

   CIBA-GEIGY
   Corporation

3. Pesticide: Propiconazole

4. Related Petition

5. Rec'd RD 4/11/89

6. Rec'd Chem. Br. 4/26/89

7. Tolerances Requested:

   0.50 ppm - Wild rice
   1.0 ppm - Stone fruit

8. Amendments and Pertinent Correspondence

9. Filing Date: 4/4/89

10. F.R. Notice of Filing

11. Method Tryout:

12. Results of Tryout:

13. Anal. Standards Rec'd Chem. Br.:

14. Certif. of Usefulness (date of letter to Company):

15. Deadlines: 45 days _____

    90 days _____

16. TOX Br. Recommendation:

17. Petition Assigned to: S. Malak

18. Chem. Br. Recommendation

19. Tolerances Established (F.R.)

Ennio

ENVIRONMENTAL PROTECTION AGENCY

[PF-516; FRL-3610-1]

Pesticide Tolerance Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the filing of pesticide petitions proposing the establishment of tolerances and/or regulations for residues of certain pesticide chemicals in or on certain agricultural commodities.

ADDRESS: By mail, submit written comments to: Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 246, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

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Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 246 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (TS-767C), Attn: Product Manager (PM) named in the petition, Environmental Protection Agency, Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460.

In person, contact the PM named in each petition at the following office location/telephone number:

Product manager	Office location/ telephone number	Address
Dennis Edwards (PM 12).	Rm. 202, CM #2, 703-557-2386.	1921 Jefferson Davis Hwy., Arlington, VA.
Phil Hutton (PM 17).	Rm. 207, CM #2, 703-557-2690.	Do.
Lois Rossi (PM 21).	Rm. 227, CM #2, 703-557-1900.	Do.
Lawrence Schnaubelt (PM 23).	Rm. 237, CM #2, 703-557-1830.	Do.
Robert Taylor (PM 25).	Rm. 237, CM #2 703-557-1800.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide (PP) and/or food and feed additive (FAP) petitions as follows proposing the establishment and/or amendment of tolerances or regulations for residues of certain pesticide chemicals in or on certain agricultural commodities.

Initial Filings

1. *PP 9F3755.* BASF Corp., Chemicals Division, 100 Cherry Hill Rd., Parsippany, NJ 07054, proposes to amend 40 CFR Part 180 by establishing a regulation to permit the residues of the herbicide 3,7-dichloro-8-quinolinecarboxylic acid in or on rice at 5.0 ppm, rice straw at 12.0 ppm, milk at 0.05 ppm, fat, meat and meat byproduct of cattle, goats, hogs, horses, and sheep at 0.05 ppm, fat and meat of poultry at 0.05 ppm, meat byproduct of poultry at 0.10 ppm, and eggs at 0.05 ppm. The proposed analytical method for determining residues is liquid gas chromatography. (PM 25)

2. *PP 9F3758.* Ciba-Geigy Corp., Agricultural Division, P.O. Box 18300, Greensboro, NC 27419, proposes to amend 40 CFR 180.434 by establishing a regulation to permit the residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolities determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalents in or on wild rice at 0.50 ppm and stone fruit at 1.0 ppm. The proposed analytical method for determining residues is gas chromatography. (PM 21)

3. *PP 9F3761.* Monsanto Co., 1101 17th St., NW., Washington, DC 20036, proposes to amend 40 CFR 180.364 by establishing a regulation to reexpress the glyphosate tolerances as written in 40 CFR 180.364 to include the application of the monoammonium salt of glyphosate and its metabolite aminomethyl-phosphonic acid. The proposed analytical method for determining residues is high-performance liquid chromatography. (PM 25)

4. *PP 9F3762.* BASF Corp., Chemicals Division, 100 Cherry Hill Rd., Parsippany, NJ 07054, proposes to amend 40 CFR 180.380 by establishing a regulation to permit the residues of the fungicide 3-(3,5-dichloro-phenyl)-5-ethenyl-5-methyl-2,4 oxazolidinedione and its metabolities containing the 3,5-dichloroaniline moiety in or on succulent beans (seed and pod) at 3.0 ppm. The proposed analytical method for determining residues is gas chromatography. (PM 21)

5. *PP 9F3763.* E. I. DuPont DeNemours & Co., Inc., Agricultural Products Department, Barley Mill Plaza, Walker's Mill 6-174, Wilmington, DE 19880-6260, proposes to amend 40 CFR Part 180 by establishing a regulation to permit the residues of the herbicide 2-[[(4,6-dimethoxypyrimidin-2-yl) aminocarbonyl]-aminosulfonyl]-N,N-dimethyl-3-pyridinecarboxamide monohydrate (DPX-V9360) in or on field corn (grain, forage, fodder, and silage) at 0.1 ppm. The proposed analytical method for determining residues is gas chromatography. (PM 25)

6. *PP 9F3784.* Dow Chemical U.S.A., P.O. Box 1706, Midland, MI 48641-1706, proposes to amend 40 CFR Part 180 by establishing a regulation to permit the residues of the herbicide haloxyfopmethyl, 2-(4-((3-chloro-5-(trifluoromethyl)-2-pyridinyl)oxy)phenoxy)propanoate, and its metabolite haloxyfop, 2-(4-((3-chloro-5-(trifluoromethyl)-pyridinyl)oxy)phenoxy) propanoic acid, free and conjugated, all expressed as haloxyfop in or on apples at 0.05 ppm. The proposed analytical method for determining residues is gas chromatography. (PM 23)

7. *PP 9F3766.* Sandoz Crop Protection Corp., 1300 East Touhy Ave., Des Plaines, IL 60018, proposes to amend 40 CFR Part 180 by establishing a regulation to permit the residues of the herbicide norflurazon, 4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-m-tolyl-3-(2H)-pyridazinone, and its desmethyl metabolite, 4-chloro-5-(amino)-2-(alpha, alpha, alpha-trifluoro-m-tolyl)-3-(2H)-pyridazinone, in or on alfalfa forage at 3.0 ppm, alfalfa hay at 5.0 ppm, alfalfa seed at 0.1 ppm, and asparagus at 0.05 ppm. The proposed analytical method for determining residues is gas chromatography. (PM 23)

8. *FAP 9H5573.* Zoecon Corp., A Sandoz Co., 12200 Denton Drive, Dallas, TX 75234, proposes to amend 40 CFR Part 185 by establishing a regulation to permit the residues of the insecticide hydroprene in food commodities exposed during treatment of food-handling establishments. (PM 17)

9. *FAP 9H5583.* BASF Corp., Chemicals Division, 100 Cherry Hill Rd., Parsippany, NJ 07054, proposes to amend 40 CFR Part 186 by establishing a regulation to permit the residues of the herbicide 3,7-dichloro-8-quinoline-carboxylic acid in or on rice bran at 15.0 ppm. The proposed analytical method for determining residues is liquid gas chromatography. (PM 25)

10. *FAP 9H5584.* E.I. DuPont DeNemours & Co., Inc., Agricultural Products Department, Barley Mill Plaza, Walker's Mill 6-174, Wilmington, DE 19880-6260, proposes to amend 40 CFR 185.4100 by establishing a regulation to permit the residues of the insecticide methomyl (S-methyl-N-[(methyl-carbomyl)oxy]thioacetimidate) in or on dried hops at 12.0 ppm. The proposed analytical method for determining residues is gas chromatography. (PM 12)

11. *FAP 9H5585.* BASF Corp., Chemicals Division, 100 Cherry Hill Rd., Parsippany, NJ 07054, proposes to amend 40 CFR 186.1850 by establishing a regulation to permit the residues of the fungicide 3-(3,5-dichloro-phenyl)-5-ethenyl-5-methyl-2,4 oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on cannery waste of succulent beans at 10.0 ppm. The proposed analytical method for determining residues is gas chromatography. (PM 21)

P2/4

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Authority: 7 U.S.C. 136a.

Dated: June 16, 1989.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 89-15413 Filed 6-28-89; 8:45 am]

BILLING CODE 6560-50-M

END OF DOCUMENT

13544

R061733

Chemical:	**Propiconazole**
PC Code:	**122101**
HED File Code	**11500 Petition Files Chemistry**
Memo Date:	**05/19/2003 12:00:00 AM**
File ID:	**DPD190499**
Accession Number:	**412-04-0136**

HED Records Reference Center
06/28/2004