



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

OFFICE OF
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

APR 18 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#9F3740 Propiconazole in/on Almonds, Almond Hulls, and Tree Nut Crop Group. Revised Section B for the ORBIT 45W formulation. Chemical# 122101, DP Barcode: D229723. CBTS#: None. MRID#: None.

FROM: Linda L. Kutney, Chemist
Tolerance Petition Team II
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

Linda L. Kutney
4/16/97

THROUGH: Elizabeth Haeberer, Acting Branch Chief
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

Elizabeth T. Haeberer

TO: Connie Welch and Kathryn Scanlon, PM Team 21
Fungicide/Herbicide Branch
Registration Division (7505C)

and

Debbie McCall, Acting Section Head
Risk Coordination and Analysis Branch
Health Effects Division (7509C)

Ciba-Geigy Corporation, the petitioner, in letters dated 4/7/95 and 7/9/96, in response to CBTS reviews of PP#9F3740 (8/24/89, 3/21/96), proposed a tolerance for almonds and almond hulls at 0.1 ppm 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 (DCBA) and expressed as parent compound.

Ciba-Geigy also proposed, in a letter dated 3/21/96, a tolerance for the crop group, tree nuts, at 0.1 ppm and for almond hulls at 0.1 ppm, for the residues of propiconazole and its metabolites, expressed as parent compound. Ciba-Geigy further requested that the existing propiconazole tolerance for pecans at 0.1 ppm be



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removed upon establishment of the proposed tree nut crop grouping tolerance for propiconazole.

Propiconazole tolerances have been established for commodities at levels ranging from 5 ppm in/on celery to 0.05 ppm in milk (40 CFR §180.434). Propiconazole is a FIFRA 88 List C chemical. A phase 4 review was completed 6/30/92.

The current petition requests that ORBIT 45W formulation (a 45% Wettable Powder, Reg. No 100-871) be included for the petition for the 0.1 ppm tolerances for almond hulls and tree nut crop group [SEE concurrent petition of 7/9/96 (D229114)].

Background

Originally, CBTS recommended for a propiconazole tolerance on pecans (PP#4F3007, 5/8/87) at 0.1 ppm. CBTS recommended in favor of propiconazole tolerances at 0.1 ppm for almonds and almond hulls, provided Section B was revised (PP#9F3740, 8/24/89); an adequate Section B was later submitted.

Residue data requirements have been satisfied for tolerances for propiconazole in/on the two representative commodities of the tree nut crop group, almonds and pecans (PP#3740, 3/21/96). Ciba-Geigy also requested a tolerance for propiconazole on the crop group, tree nuts, at 0.1 ppm. The second supplemental labeling for Orbit™ (EPA Reg. No. 100-702) and Orbit™ Gel (EPA Reg. No. 100-737) included directions for hazelnuts (filberts) (PP#3740, 3/21/96).

Ciba-Geigy's concurrent petition of 7/9/96 (D229114) included revised Sections B and F, and requested a tolerance for the crop group tree nuts at 0.1 ppm and for almond hulls at 0.1 ppm, for residues of propiconazole and its metabolites expressed as parent compound. Ciba-Geigy further requested the existing propiconazole tolerance for pecans at 0.1 ppm be removed upon establishment of the proposed tree nut crop grouping for propiconazole. Labels for ORBIT GEL and ORBIT FUNGICIDE on almonds and filberts were included.

Ciba-Geigy's current petition of 9/7/96 (D229723) requested that EPA consider adding the "newly approved ORBIT 45W formulation to PP No. 9F3740." A label for the ORBIT 45W formulation was included.

RECOMMENDATIONS

CBTS reiterates its recommendation (in a concurrent memorandum, Dbarcode #234296, 3/13/97) against establishment of the proposed propiconazole tolerance in or on tree nuts at 0.1 ppm, pending

resolution of deficiencies on the ORBIT 3.6E label.

In addition, a revised Section B and a label change including the volume of water necessary to ensure coverage in the directions is necessary for use of ORBIT 3.6 on filberts.

CBTS has recommended that directions be provided for all individual nut crops to be treated, OR, for the entire nut crop group, for all labels of all formulations to be used on nut crops, including ORBIT 3.6E, ORBIT GEL and ORBIT FUNGICIDE, and ORBIT 45W.

A DRES run may be conducted at this time, if necessary (a run was requested with the previous petition). The DRES calculations should use the tree nut crop group and almond hulls at 0.1 ppm.

CBTS Deficiency PP#9F3740, 3/21/96

"The following restrictions should be added to the proposed use directions for Orbit 3.6E on filberts: (A)'Do not graze livestock in treated areas or cut treated cover crops for feed.' (B)'Do not tank mix with any pesticidal product which does not have a registered use on filberts.'" These restrictions should also be included in other formulations of ORBIT used on the nut crop group.

Petitioner's Response

Ciba-Geigy has submitted a revised label for ORBIT 45W on filberts.

CBTS Response

The deficiency concerning prohibiting grazing livestock in treated areas or cutting treated cover crops for feed is resolved for use of ORBIT 45W on almonds and filberts, in the revised label.

CBTS Deficiency PP#9F3740, 3/21/96

Ciba-Geigy must indicate the recommended volume of water necessary to ensure coverage in the directions for filberts, for the ORBIT 3.6E label.

Petitioner's Response

Ciba-Geigy has submitted the recommended volume of water necessary to ensure coverage in their revised Section B for ORBIT 45W and on the proposed labels, but not for use of ORBIT 3.6 on filberts.

CBTS Response

The recommended label change including the volume of water necessary to ensure coverage in the directions for filberts is resolved for ORBIT 45W, but not for use of ORBIT 3.6 on filberts (discussed in a concurrent petition).

Detailed Considerations

Proposed Use

The general directions state that "if using Orbit 45W in a tank mixture, observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations which appear on the tank mix product label. No label dosage should be exceeded, and the most restrictive label precautions and limitations should be followed. This product should not be mixed with any product which prohibits such mixing."

On almonds, the label states "Apply 0.25 - 0.5 lb ORBIT at the 5-10% bloom and 50-100% bloom. For ground applications, a minimum of 100 gal/A of water is recommended. For aerial applications, a minimum of 20 gal/A is recommended. The directions also state, "Do not graze livestock in treated areas or cut treated cover crops for feed."

On filberts (hazelnuts), the label states "Apply 0.3 - 0.5 lb of ORBIT 45W per acre with sufficient water to obtain thorough coverage. Begin when green leaf tissue becomes visible and continue on 2-3 week intervals. Do not apply more than 2 lb of ORBIT 45W per acre per season."

The general directions for ORBIT 45W contain the following restriction, "Do not apply more than 400 g ai of propiconazole (32 fl. oz ORBIT GEL, ORBIT FUNGICIDE, ORBIT 45W) per acre per season." NOTE: This may be mistaken to mean, "Do not apply more than 32 oz of ORBIT 45W, a wettable powder). The sentence should be modified in the proposed label for ORBIT 45W to read, "Do not apply more than 400 g ai of propiconazole (32 fl oz of ORBIT, 32 fl oz of ORBIT GEL, or 2 lb of ORBIT 45W) per season."

In addition, CBTS notes that ORBIT 45W contains the label "CAUTION," and not "WARNING," as do other ORBIT labels. The label for ORBIT 45W should contain the following language to be consistent with other ORBIT labels, "WARNING/AVISO: Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.) This statement should be present on the ORBIT 45W and ORBIT 3.6 labels."

The use patterns for almonds and filberts are similar to the use

pattern on pecans for which the tolerance was established (PP#4F3007, 5/8/87).

Magnitude of Residue

No residue data were submitted with this amended petition. The proposed use of propiconazole on filberts is similar to the use pattern on pecans for which the tolerance was established, previously, at 0.1 ppm (PP#4F3007, 5/8/87). The residues of propiconazole on filberts (hazelnuts) are not expected to exceed the proposed group tolerance of 0.1 ppm.

Other Considerations

A Codex MRL exists on pecans at 0.05 ppm for propiconazole per se. A Mexican limit exists on walnuts at 0.1 ppm for propiconazole "presumed." No Canadian limit has been established for tree nuts or any member of the tree nut crop group (PP#9F3740, 3/21/96).

In addition to the numerical difference between the Codex MRL on pecans at 0.05 ppm and the requested propiconazole tolerance on the tree nut crop group at 0.1 ppm, there is a difference between the Codex and U.S. definition of residue. The U.S. definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), while the Codex and Mexican definitions are restricted to parent. There are no Canadian limits on tree nuts, however the propiconazole residue is defined as parent and metabolites with the 2,4-dichlorophenyl-1-methyl moiety (PP#9F3740, 3/21/96).

An International Residue Limit Status form was completed in conjunction with the previous review (PP#9F3740, 3/21/96).

cc: RF, SF, PP#9F3740, circ., Kutney, 7509C: CBTS, Rm 804D,
305-5351, LLK: 3/10/97
R/I: CBTS Team II: 3/26/97; Act. Br. Chief: Elizabeth Haeberer:
4/1/97

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of
Document



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

APR 18 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#9F3740 Propiconazole in/on Almonds, Almond Hulls, and Tree Nut Crop Group. Revised Section B for the ORBIT 45W formulation. Chemical# 122101, DP Barcode: D229723. CBTS#: None. MRID#: None.

FROM: Linda L. Kutney, Chemist
Tolerance Petition Team II
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

Linda L. Kutney
4/18/97

THROUGH: Elizabeth Haeberer, Acting Branch Chief
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

Elizabeth T. Haeberer

TO: Connie Welch and Kathryn Scanlon, PM Team 21
Fungicide/Herbicide Branch
Registration Division (7505C)

and

Debbie McCall, Acting Section Head
Risk Coordination and Analysis Branch
Health Effects Division (7509C)

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Ciba-Geigy also proposed, in a letter dated 3/21/96, a tolerance for the crop group, tree nuts, at 0.1 ppm and for almond hulls at 0.1 ppm, for the residues of propiconazole and its metabolites, expressed as parent compound. Ciba-Geigy further requested that the existing propiconazole tolerance for pecans at 0.1 ppm be



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removed upon establishment of the proposed tree nut crop grouping tolerance for propiconazole.

Propiconazole tolerances have been established for commodities at levels ranging from 5 ppm in/on celery to 0.05 ppm in milk (40 CFR §180.434). Propiconazole is a FIFRA 88 List C chemical. A phase 4 review was completed 6/30/92.

The current petition requests that ORBIT 45W formulation (a 45% Wettable Powder, Reg. No 100-871) be included for the petition for the 0.1 ppm tolerances for almond hulls and tree nut crop group [SEE concurrent petition of 7/9/96 (D229114)].

Background

Originally, CBTS recommended for a propiconazole tolerance on pecans (PP#4F3007, 5/8/87) at 0.1 ppm. CBTS recommended in favor of propiconazole tolerances at 0.1 ppm for almonds and almond hulls, provided Section B was revised (PP#9F3740, 8/24/89); an adequate Section B was later submitted.

Residue data requirements have been satisfied for tolerances for propiconazole in/on the two representative commodities of the tree nut crop group, almonds and pecans (PP#3740, 3/21/96). Ciba-Geigy also requested a tolerance for propiconazole on the crop group, tree nuts, at 0.1 ppm. The second supplemental labeling for Orbit™ (EPA Reg. No. 100-702) and Orbit™ Gel (EPA Reg. No. 100-737) included directions for hazelnuts (filberts) (PP#3740, 3/21/96).

Ciba-Geigy's concurrent petition of 7/9/96 (D229114) included revised Sections B and F, and requested a tolerance for the crop group tree nuts at 0.1 ppm and for almond hulls at 0.1 ppm, for residues of propiconazole and its metabolites expressed as parent compound. Ciba-Geigy further requested the existing propiconazole tolerance for pecans at 0.1 ppm be removed upon establishment of the proposed tree nut crop grouping for propiconazole. Labels for ORBIT GEL and ORBIT FUNGICIDE on almonds and filberts were included.

Ciba-Geigy's current petition of 9/7/96 (D229723) requested that EPA consider adding the "newly approved ORBIT 45W formulation to PP No. 9F3740." A label for the ORBIT 45W formulation was included.

RECOMMENDATIONS

CBTS reiterates its recommendation (in a concurrent memorandum, Dbarcode #234296, 3/13/97) against establishment of the proposed propiconazole tolerance in or on tree nuts at 0.1 ppm, pending

resolution of deficiencies on the ORBIT 3.6E label.

In addition, a revised Section B and a label change including the volume of water necessary to ensure coverage in the directions is necessary for use of ORBIT 3.6 on filberts.

CBTS has recommended that directions be provided for all individual nut crops to be treated, OR, for the entire nut crop group, for all labels of all formulations to be used on nut crops, including ORBIT 3.6E, ORBIT GEL and ORBIT FUNGICIDE, and ORBIT 45W.

A DRES run may be conducted at this time, if necessary (a run was requested with the previous petition). The DRES calculations should use the tree nut crop group and almond hulls at 0.1 ppm.

CBTS Deficiency PP#9F3740, 3/21/96

"The following restrictions should be added to the proposed use directions for Orbit 3.6E on filberts: (A)'Do not graze livestock in treated areas or cut treated cover crops for feed.' (B)'Do not tank mix with any pesticidal product which does not have a registered use on filberts.'" These restrictions should also be included in other formulations of ORBIT used on the nut crop group.

Petitioner's Response

Ciba-Geigy has submitted a revised label for ORBIT 45W on filberts.

CBTS Response

The deficiency concerning prohibiting grazing livestock in treated areas or cutting treated cover crops for feed is resolved for use of ORBIT 45W on almonds and filberts, in the revised label.

CBTS Deficiency PP#9F3740, 3/21/96

Ciba-Geigy must indicate the recommended volume of water necessary to ensure coverage in the directions for filberts, for the ORBIT 3.6E label.

Petitioner's Response

Ciba-Geigy has submitted the recommended volume of water necessary to ensure coverage in their revised Section B for ORBIT 45W and on the proposed labels, but not for use of ORBIT 3.6 on filberts.

CBTS Response

The recommended label change including the volume of water necessary to ensure coverage in the directions for filberts is resolved for ORBIT 45W, but not for use of ORBIT 3.6 on filberts (discussed in a concurrent petition).

Detailed Considerations

Proposed Use

The general directions state that "if using Orbit 45W in a tank mixture, observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations which appear on the tank mix product label. No label dosage should be exceeded, and the most restrictive label precautions and limitations should be followed. This product should not be mixed with any product which prohibits such mixing."

On almonds, the label states "Apply 0.25 - 0.5 lb ORBIT at the 5-10% bloom and 50-100% bloom. For ground applications, a minimum of 100 gal/A of water is recommended. For aerial applications, a minimum of 20 gal/A is recommended. The directions also state, "Do not graze livestock in treated areas or cut treated cover crops for feed."

On filberts (hazelnuts), the label states "Apply 0.3 - 0.5 lb of ORBIT 45W per acre with sufficient water to obtain thorough coverage. Begin when green leaf tissue becomes visible and continue on 2-3 week intervals. Do not apply more than 2 lb of ORBIT 45W per acre per season."

The general directions for ORBIT 45W contain the following restriction, "Do not apply more than 400 g ai of propiconazole (32 fl. oz ORBIT GEL, ORBIT FUNGICIDE, ORBIT 45W) per acre per season." NOTE: This may be mistaken to mean, "Do not apply more than 32 oz of ORBIT 45W, a wettable powder). The sentence should be modified in the proposed label for ORBIT 45W to read, "Do not apply more than 400 g ai of propiconazole (32 fl oz of ORBIT, 32 fl oz of ORBIT GEL, or 2 lb of ORBIT 45W) per season."

In addition, CBTS notes that ORBIT 45W contains the label "CAUTION," and not "WARNING," as do other ORBIT labels. The label for ORBIT 45W should contain the following language to be consistent with other ORBIT labels, "WARNING/AVISO: Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.) This statement should be present on the ORBIT 45W and ORBIT 3.6 labels."

The use patterns for almonds and filberts are similar to the use

pattern on pecans for which the tolerance was established (PP#4F3007, 5/8/87).

Magnitude of Residue

No residue data were submitted with this amended petition. The proposed use of propiconazole on filberts is similar to the use pattern on pecans for which the tolerance was established, previously, at 0.1 ppm (PP#4F3007, 5/8/87). The residues of propiconazole on filberts (hazelnuts) are not expected to exceed the proposed group tolerance of 0.1 ppm.

Other Considerations

A Codex MRL exists on pecans at 0.05 ppm for propiconazole per se. A Mexican limit exists on walnuts at 0.1 ppm for propiconazole "presumed." No Canadian limit has been established for tree nuts or any member of the tree nut crop group (PP#9F3740, 3/21/96).

In addition to the numerical difference between the Codex MRL on pecans at 0.05 ppm and the requested propiconazole tolerance on the tree nut crop group at 0.1 ppm, there is a difference between the Codex and U.S. definition of residue. The U.S. definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), while the Codex and Mexican definitions are restricted to parent. There are no Canadian limits on tree nuts, however the propiconazole residue is defined as parent and metabolites with the 2,4-dichlorophenyl-1-methyl moiety (PP#9F3740, 3/21/96).

An International Residue Limit Status form was completed in conjunction with the previous review (PP#9F3740, 3/21/96).

cc: RF, SF, PP#9F3740, circ., Kutney, 7509C: CBTS, Rm 804D,
305-5351, LLK: 3/10/97
R/I: CBTS Team II: 3/26/97; Act. Br. Chief: Elizabeth Haerberer:
4/1/97



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MAR 27 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#9F3740 Propiconazole in/on Almonds, Almond Hulls, and Tree Nut Crop Group. Revised Section B and Section F for ORBIT and ORBIT GEL. Chemical# 122101, DP Barcodes: D229114 and D234297. CBTS#: 17852. MRID#: None.

FROM: Linda L. Kutney, Chemist *Linda L. Kutney*
Tolerance Petition Team II
Chemistry Branch I: Tolerance Support 3/12/97
Health Effects Division (7509C)

THROUGH: Elizabeth Hasberer, Acting Branch Chief *Elizabeth T. Hasberer*
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

TO: Connie Welch and Kathryn Scanlon, PM Team 21
Fungicide/Herbicide Branch
Registration Division (7505C)

and

Debbie McCall, Acting Section Head
Risk Coordination and Analysis Branch
Health Effects Division (7509C)

Ciba-Geigy Corporation, the petitioner, in letters dated 4/7/95 and 7/9/96, presented revised Sections B and F, in response to CBTS reviews of PP#9F3740 (8/24/89, 3/21/96). Ciba-Geigy proposes a tolerance for almonds and almond hulls at 0.1 ppm 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 (DCBA) and expressed as parent compound.

Ciba-Geigy, in a letter dated 3/21/96, submitted a revised Section B and Section F requesting a tolerance for the crop group tree nuts at 0.1 ppm and for almond hulls at 0.1 ppm, for the residues of propiconazole and its metabolites, expressed as parent compound. Ciba-Geigy further requested that the existing propiconazole



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tolerance for pecans at 0.1 ppm be removed upon establishment of the proposed tree nut crop grouping tolerance for propiconazole. Propiconazole tolerances have been established for commodities at levels ranging from 5 ppm in/on celery to 0.05 ppm in milk (40 CFR §180.434).

Propiconazole is a FIFRA 88 List C chemical. A phase 4 review was completed 6/30/92.

Background

CBTS originally recommended for a propiconazole tolerance on pecans (PP#4F3007, 5/8/87) at 0.1 ppm. Ciba-Geigy subsequently requested propiconazole tolerances at 0.1 ppm for almonds and almond hulls and CBTS recommended in favor of the tolerances, provided the Section B was revised (PP#9F3740, 8/24/89), which was subsequently done.

Residue data requirements have been satisfied for tolerances for propiconazole in/on the two representative commodities of the tree nut crop group, almonds and pecans (PP#3740, 3/21/96). Ciba-Geigy also requested a tolerance for propiconazole on the crop group, tree nuts, at 0.1 ppm. The second revised labeling for Orbit™ (EPA Reg. No. 100-702) and Orbit™ Gel (EPA Reg. No. 100-737) included directions for hazelnuts (filberts) (PP#3740, 3/21/96).

Ciba-Geigy's present request of 7/9/96 (D229114) includes revised labels for ORBIT GEL and ORBIT FUNGICIDE on almonds and filberts, and a revised Section B and F, requesting a tolerance for the crop group tree nuts at 0.1 ppm and for almond hulls at 0.1 ppm, for residues of propiconazole and its metabolites expressed as parent compound. Ciba-Geigy further requested the existing propiconazole tolerance for pecans at 0.1 ppm be removed upon establishment of the proposed tree nut crop grouping for propiconazole.

CBTS Deficiency PP#9F3740, 3/21/96

"The following restrictions should be added to the proposed use directions for Orbit 3.6E on filberts: (A) 'Do not graze livestock in treated areas or cut treated cover crops for feed.' (B) 'Do not tank mix with any pesticidal product which does not have a registered use on filberts.'"

Petitioner's Response

Ciba-Geigy has submitted a revised labels for ORBIT GEL and ORBIT FUNGICIDE with the requested revisions, but not for ORBIT 3.6E.

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CBTS Response

The deficiency concerning prohibiting grazing livestock in treated areas or cutting treated cover crops for feed is resolved for use of ORBIT GEL and ORBIT FUNGICIDE on almonds and filberts, in the revised labels for ORBIT GEL and ORBIT FUNGICIDE.

The restriction, "Do not tank mix with any pesticidal product which does not have a registered use on filberts," has been added to the General Information section of the label, stating that ORBIT GEL and ORBIT FUNGICIDE "should not be mixed with any product which prohibits such mixing." In addition, it directs that, for ORBIT GEL and ORBIT FUNGICIDE, "(...No label dosage rate should be exceeded, and the most restrictive label precautions and limitations should be followed. Tank mixtures or other applications of products reference(d) on this label are permitted only in those states in which the referenced products are registered)."

The deficiency prohibiting tank mixing with any pesticidal product which does not have a registered use on filberts, is resolved for use of ORBIT GEL and ORBIT FUNGICIDE. However, these deficiencies were cited by CBTS for the ORBIT 3.6E label, not the ORBIT GEL and ORBIT FUNGICIDE label. No additional information was provided for the use of ORBIT 3.6E on filberts. These deficiencies remain outstanding for the use of the ORBIT 3.6E formulation on filberts.

CBTS Deficiency PP#9F3740, 3/21/96

Ciba-Geigy must indicate the recommended volume of water necessary to ensure coverage in the directions for filberts. However, this deficiency was for the ORBIT 3.6E label, not the ORBIT GEL and ORBIT FUNGICIDE labels.

Petitioner's Response

Ciba-Geigy has submitted the recommended volume of water necessary to ensure coverage in their revised labels for ORBIT GEL and ORBIT FUNGICIDE, but not for the use of ORBIT 3.6 on filberts.

CBTS Response

The recommended label change for including the volume of water necessary to ensure coverage in the directions for filberts is resolved for ORBIT GEL and ORBIT FUNGICIDE. The deficiency remains outstanding for ORBIT 3.6E.

Recommendations

CBTS recommends against establishment of the proposed propiconazole tolerance in or on tree nuts at 0.1 ppm for the reasons outlined below, pending resolution concerning deficiencies in the label for ORBIT 3.6E.

CBTS further recommends that directions be provided for all individual nut crops to be treated, OR, for the entire nut crop group, for all labels of all formulations to be used on nut crops; i.e., ORBIT 3.6E, ORBIT GEL and ORBIT FUNGICIDE and ORBIT 45W.

A DRES run may be conducted at this time, if necessary (a run was requested with the previous petition). The DRES calculations should use the tree nut crop group and almond hulls at 0.1 ppm.

Detailed Considerations

Proposed Use

The general directions state that "if using the products, Orbit™ and Orbit™ Gel in a tank mixture, observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations which appear on the tank mix product label."

"ORBIT GEL and ORBIT FUNGICIDE are to be applied on almonds during the 5-10% bloom and 50-100% bloom stage at a rate of 4-8 fl oz/A. For ground applications, a minimum of 100 gal/A spray volume is recommended. For aerial applications, a minimum spray volume of 20 gal/A is recommended. The directions also state, "Do not graze livestock in treated areas or cut treated cover crops for feed."

The proposed use directions for filberts (hazelnuts) state that ORBIT GEL and ORBIT FUNGICIDE are to be applied at 5-8 fl oz/A with sufficient water to obtain thorough coverage. Applications begin when green leaf tissue becomes visible and continues on 2-3 week intervals. Do not apply more than 32 fl oz of the formulation (400 g ai) per acre per season. The use pattern is similar to the use pattern on pecans for which the tolerance was established (PP#4F3007, 5/8/87).

Magnitude of Residue

No residue data were submitted with this amended petition. The proposed use of propiconazole on filberts is similar to the use pattern on pecans for which the tolerance was established, previously, at 0.1 ppm (PP#4F3007, 5/8/87). The residues of propiconazole on filberts (hazelnuts) are not expected to exceed the proposed group tolerance of 0.1 ppm.

Other Considerations

A Codex MRL exists on pecans at 0.05 ppm for propiconazole per se. A Mexican limit exists on walnuts at 0.1 ppm for propiconazole "presumed." No Canadian limit has been established for tree nuts or any member of the tree nut crop group (PP#9F3740, 3/21/96).

In addition to the numerical difference between the Codex MRL on pecans at 0.05 ppm and the requested propiconazole tolerance on the tree nut crop group at 0.1 ppm, there is a difference between the Codex and U.S. definition of residue. The U.S. definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), while the Codex and Mexican definitions are restricted to parent. There are no Canadian limits on tree nuts, however the propiconazole residue is defined as parent and metabolites with the 2,4-dichlorophenyl-1-methyl moiety (PP#9F3740, 3/21/96).

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305-5351, LLK: 3/12/97
R/I: CBTS Team II: 3/27/97; Act. Br. Chief: Elizabeth Haeberer:
date

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of
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17

DIETARY EXPOSURE BRANCH, HED
DATA REVIEW QUICK FORM

AUG 24 1989

Date: _____

MEMORANDUM

SUBJECT: Petition Review for Establishment
of Tolerance(s).
Evaluation of Analytical Method(s)
and Residue Data.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division, H7509C *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division, H7509C *RH*

TO: Hoyt Jamerson PM 43
Registration Division, H7505C

and

Toxicology Branch - HFA Support
Health Effects Division, H7509C

1. Petition No(s): 9F3740
2. DEB No(s): 5164, 5165 HED No.: 9-1161
3. MRID No(s): 410213-00, -01, -02
4. Pesticide(s): Propiconazole
5. Tolerance Proposal (RACs & Levels):
0.1 ppm - almonds, almond hulls
6. Petitioner: Ciba-Geigy Corporation

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7. Tolerance Expression: Combined residues of the fungicide
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.

8. Established Pesticide Tolerances: 40 CFR 180.434

0.2 Bananas	0.5(T) Grass, Forage Exp. 6/21/91	0.1 Pecans
0.1 Barley, Grain	5.0(T) Grass, Hay Exp. 6/21/91	0.2 Poultry, Kidney & Liver
1.5 Barley, Straw	10.0(T) Grass Seed Screening	0.1 Poultry (Meat, Fat, MBYP
0.2 Cattle, Kidney & Liver	Exp. 6/21/91	Except Kidney & Liver)
2.0(T) Cattle, Kidney & Liver	0.2 Hogs, Kidney & Liver	0.1 Rice, Grain
Exp. 6/21/91	2.0 Hogs, Kidney & Liver	3.0 Rice, Straw
0.1 Cattle (Meat, Fat, MBYP	Exp. 6/21/91	0.1 Rye, Grain
Except Kidney & Liver)	0.1 Hogs (Meat, Fat, MBYP	1.5 Rye, Straw
0.1 Eggs	Except Kidney & Liver)	0.2 Sheep, Kidney & Liver
0.2 Goats, Kidney & Liver	0.2 Horses, Kidney & Liver	2.0(T) Sheep, Kidney & Liver
2.0(T) Goats, Kidney & Liver	2.0(T) Horses, Kidney & Liver	Exp. 6/21/91
Exp. 6/21/91	Exp. 6/21/91	0.1 Sheep (Meat, Fat, MBYP
0.1 Goats (Meat, Fat, MBYP	0.1 Horses (Meat, Fat, MBYP	Except Kidney & Liver)
Except Kidney & Liver)	Except Kidney & Liver)	0.1 Wheat, Grain
	0.05 Milk	1.5 Wheat, Straw
Administrative Guidelines: None		
Tolerances Pending:		
0.1 Almonds 3/23/89	0.5 Grass, Forage 2/22/89	0.5 Legume Vegetables
0.1 Almonds, Hulls 3/23/89	5.0 Grass, Hay 2/22/89	(Succulent) 10/12/88
2.0 Cattle, Kidney &	10 Grass, Seed, Screenings	0.2 Peanuts 10/12/88
Liver 4/19/89	3/15/89	20 Peanuts, Hay 10/12/88
5.0 Celery 10/12/88	2.0 Hogs, Kidney &	1 Peanuts, Hulls 10/12/88
10.0 Corn, Fodder 10/12/88	Liver 4/19/89	0.1 Pineapples 10/12/88
10.00 Corn, Forage 10/12/88	2.0 Horses, Kidney &	0.1 Pineapples, Fodder
0.1 Corn, Grain 10/12/88	Liver 4/19/89	10/12/88
0.1 Corn, Sweet (K+CWR)	0.5 Legume Vegetables	0.50 Rice, Wild 6/29/89
10/12/88	(Dried) 10/12/88	2.0 Sheep, Kidney &
2.0 Goats, Kidney &	5.0 Legume Vegetables,	Liver 4/19/89
Liver 4/19/89	Foliage 10/12/88	1.0 Stone Fruit 6/29/89

11. Is Pesticide a Registration Standard Chemical? (Yes/No) No
 If yes, date Guidance Document issued: _____
12. Letter(s) of Authorization (if applicable): _____
N/A
13. Formulation(s): Orbit 3.6E, EPA Reg. No. 100-702, an
emulsifiable concentrate containing 3.6 lbs ai (propiconazole)
per gallon of formulated product.
14. Inerts Status: Under RD purview.
15. Manufacturing Process: Discussed in 1/7/82 review, J. Worthington,
PP# 1G2530. Modified by MRID#s 405837-01 thru -03 (see
2/7/89 review, H. Fonouni, PP# 9F3706). Impurities should pose
no residue problem.

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16. Proposed Use(s): Orbit 3.6E (note #44; also see #47)

Almonds

For control of brown rot blossom blight, apply 4 fl. oz. of Orbit 3.6E per acre at 5-10% bloom and again at 50-100% bloom. Under severe disease pressure a maximum of 8 fl. oz. may be used per application.

NOTE - Orbit is most effective when applied before a rainfall and is allowed to dry.

Orbit can be applied by either ground or aerial application. For ground applications, a minimum of 100 gallons per acre is recommended. For aerial applications, a minimum of 20 gallons per acre is recommended.

8 fl. oz. formulation $\cong$ 100 g. ai $\cong$ 0.22 lb ai

17. Plant Metabolism Data on: _____

peanuts, wheat, and grapes

(see extensive review by A. Smith, 5/15/84, PP# 4E3007)

18. Plant Residues Comprised of: parent (CGA-64250), free and
supe-conjugated hydroxy metabolites with the intact parent ring
system (dichlorophenyl, triazole, and dioxolane) and others without
the dioxolane ring portion. See ref. cited in #17 for full review.

19. Plant Metabolism Data Translatable Here: _____

All, per #17

20. Nature of Plant Metabolism on the Subject RAC(s) of This Petition
is is not adequately defined.

The Residue of Concern is: per 40 CFR 180.434; see #7.

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21. Animal Metabolism Data on: _____

/ = propiconazole

The metabolism of CGA-64250 in lactating goats and rats has been reported (pp# 4F3007, memorandum of 5/15/1984 by A. Smith). 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.

23. Animal Metabolism Data Applicable Here: Goat24. Nature of Animal Metabolism Data (is) is not adequately defined.The Residue of Concern is: per 40 CFR 180.434; see #7.

25. Analytical Method(s) (Give Reference and/or Brief Description)

Almond samples were analyzed for residues of propiconazole and metabolites containing the 2-4-dichlorobenzoic acid moiety by Analytical Method AG-454 (subsequently revised in a revised format as AG-454A, MRID# A00224-01).

AG-454A (capillary GLC with EC detection) has been sent to FDA (memo of S. Malak, 5/28/87, copy with PP# 4F3007) for inclusion in PAM II as the crops enforcement method.

Representative chromatograms are submitted with this petition for almonds.

For discussion of the details of the method, see 5/28/87 (S. Malak), PP# 4F3074/4F3007/4E3026 review (MTO evaluation).

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26. Has there been a Method Trial? (Yes, No) Yes (successful).
 If yes, provide details: for AG-454A on wheat grain and straw and pecan nutmeats; see 3/11/87 (S. Malak; MTO request), 4/27/87 (E. Greer, et al.; MTO report), and 5/28/87 (S. Malak; MTO evaluation) reviews, PP#s 4F3007/4F3074/4E3026.
Continued under #45.
27. Residues Determined by Method(s): Parent and its metabolites containing the 2,4-dichlorophenyl moiety. Residues are converted to 2,4-dichlorobenzoic acid (DCBA) ester for quantitation (single GLC peak).
28. Method Validation (RACs/"spike chemical"/fortification level(s)/recovery range/average recovery):

<u>almond nutmeats/propiconazole/</u>	<u>0.05 ppm/</u>	<u>63.2-97.1%</u>	} <u>78.4% (n=8)</u>
<u>" " / " /</u>	<u>0.20 " /</u>	<u>62.7-77.8%</u>	
<u>" hulls / " /</u>	<u>0.05-1.0 ppm /</u>	<u>51.3-80.5% / 70.9% (n=8)</u>	
29. Method Validation (limit of detection and/or sensitivity in ppm):
 Parent: 0.05 ppm
 Metabolite(s) (specify): 0.05 ppm (all regulated species, converted/measured as DCBA methyl ester)
30. Method Validation (state crops and control values reported):
almond hulls and nutmeats, < 0.05 ppm
(quantitated as DCBA methyl ester and reported in propiconazole equivalents)
31. Adequate Analytical Method(s) (are) are not Available for Enforcement Purposes.
 These Method(s) are located: sent to FDA 5/28/87 for inclusion in PAM II. PIB/FOD (C. Furlow) can supply in interim.

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32. PAM I Multiresidue Methods Data are available for parent pesticide tested via Protocols I II III IV (circle, as applicable). Additional multiresidue test information for parent compound that is needed: None. Raw data are in MRID# 401001-01, and were reviewed in the S. Malak memo of 4/28/87, PP#s AF3074/AF3007/4E3026.
33. PAM I Multiresidue Methods Data are available for metabolite(s) tested via Protocols I II III IV (circle, as applicable). Additional multiresidue test information for metabolite(s) that is needed: Available for representative metabolites: alkanol (CGA-91305), β -hydroxy CGA-118244, and CGA-71019 (1,2,4-triazole). Same citation and review as #32. No additional data required.
34. Residue Data (RAC(s) and Processed Commodities)

Almonds: 4 field trials in CA (3 different locations), 1985
>2 different varieties
foliar applications using ground equipment, 400-500 gal. spray/A/appl'd
2 or 5 applications beginning @ pink bud (proposed use permits 2 applications)
100 or 200 g ai rate/application (proposed rate = 50-100g ai/A/appl'd)
PHI's of 89-200 days (proposed use - at pink bud plus at 50% bloom-buils in a
PHI of ca 160-200 days based on these trials)
Almond samples were collected at "normal" harvest (maturity). Samples were
not cleaned or washed.
Harvested samples (hulls, nutmeats) were held in frozen storage (-15°C) for
12-14 months prior to extraction and analysis by EC-GC. Analysis
occurred within 2 weeks of extraction.
Two subsamples per treatment regimen were analyzed.

almond hulls	2 x 100g ai/A/appl'd	161-200d PHI	<0.05-0.05 ppm	(n=8)	} 1X prop. use
" nutmeats	"	"	<0.05 ppm	"	
" hulls	2 x 200	181-199d PHI	<0.05-0.15 ppm	(n=4)	} 2X proposed
" nutmeats	"	"	<0.05 ppm	"	

Other data (5 applications @ 1-2X rate, shaker PHI's) are irrelevant to
the proposed use; these data indicate higher residues at shorter
PHI's (nuts present during application). Those residues were
attributed to surface contact rather than translocation.

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35. Frozen Storage Stability Data are are not Available.

If yes, give RACs/fortification levels/length of storage/recovery range/conditions of storage (°C): Soybeans and peanuts data are available (see 5/15/84 review of A. Smith, PP#4F3007) for propiconazole from samples stored (5°F) for 6 and 25 months, respectively. Residues were not appreciably reduced. (Note: peanut nutmeat data was deemed aberrantly high and disregarded.)

36. Regional Registration is is not involved.

If yes, list States in which use is sought: _____

If yes, indicate/explain (see 51 FR 11341, 4/2/86 - Policy on Minor Uses) if a bona fide "Minor Use" is involved: _____

37. Geographic Representation is is not adequate. If no, list RAC(s) and States from which additional data are needed: _____

CA is the only commercial production area of almonds in the USA.

38. Residues will not exceed proposed ^{0.1 ppm} tolerance(s) on (commodities) _____

almonds or almond hulls (under the proposed use conditions)

but may exceed proposed tolerance(s) on (commodities) _____

39. Livestock Feeding Studies on (species): lactating dairy cows and laying hens (see 7/12/84 A. Smith review, PP#4F3074).

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40. Animal Feeding Levels: cows: 0, 15, 75, and 150 ppm of propiconazole for 28 days. hens: 0, 7.5, 37.5, and 75 ppm of propiconazole for 28 days.
41. Animal Residue Ingestion Levels from Proposed RAC Tolerance(s)
Levels (proposed ^{0.1 ppm} tolerance level x ^{25%} percent in diet): 0.025 ppm in beef cattle; 0.025 ppm in dairy cattle/goats; N/A ppm in hogs; N/A ppm in horses; N/A ppm in sheep; N/A ppm in poultry.
42. Livestock Tolerances are Adequate in (species) cattle and milk
but not adequate in N/A
43. Livestock Tolerances Need to be Established: Yes/No. If yes, species/levels: Existing tolerances are adequate.
44. Other Comments: Tilt and Orbit are identical formulations of propiconazole. Tilt registrations are for vegetables while Orbit registrations are primarily for tree crops. Tilt 3.6E = EPA Reg. No. 100-617; Orbit 3.6E = EPA Reg. No. 100-702.
45. Other Considerations: A successful method trial has also been conducted on AG-517 for beef liver, milk, and eggs; see 3/11/87 (S. Malak), 4/27/87 (E. Greer, et al.), and 5/28/87 (S. Malak) memoranda, PP# 4F3074. This method has been forwarded to FDA for PAM II as the enforcement method/animal commodities.
46. Additional Information Needed: _____

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47. Further Considerations: ① No aerial data are provided. Since the proposed use is ≤ bloom stage (prior to nut formation), and since the submitted residue data suggest residues (from trials in which almond orchards were treated after nuts began to form) as a result of surface contact rather than translocation, no aerial data are being requested to supplement the existing residue data base from ground applications.
- ② The following restrictions should be added to the proposed use directions (almonds for Orbit 3.6E: (A) "Do not graze livestock in treated areas or cut treated cover crops for feed." (B) "Do not tank mix with any pesticidal product which does not have a registered use on almonds." A revised Section B for Orbit 3.6E should be submitted incorporating these restrictions.
- ③ Additional residue data are available on a tree nut crop (pecans) to supplement the submitted trials with almonds. See PP# 4F3007. A tolerance of 0.1 ppm is established for pecans under 40 CFR 180.434.

48. RECOMMENDATIONS: Provided the petitioner submits the requested revised Section B (see #47②, above), and toxicological considerations permitting, DEB will be able to recommend for the proposed tolerances (see #5) for 40 CFR 180.434.
49. Other Comments Under Recommendations: PM, please note Orbit 3.6E label states on p.1 its EPA Reg. No. is 100-702 and on p.2 its EPA Reg. No. is 100-617. This inconsistency should be corrected by the registrant. (100-617 is Tilt 3.6E; see #44.)
50. Compatibility with Codex Tolerances? (Explain) No; Codex regulates parent only. In USA, parent and closely related (structurally) metabolites are all regulated via a total residue method which converts all to DCBA methyl ester.

ATTACHMENT(S): (1) International Residue Limits Status Sheet

cc: RF, Circ, Reviewer, PP# 9F3740, RDSchmitt, (Eldredge) PMSD/ISB.
 Approved: RSQuick RML 8/24/89; RALoranger R. Loranger 8/24/89.

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INTERNATIONAL RESIDUE LIMIT STATUSCHEMICAL PropiconazoleCODEX NO. 160

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

propiconazole

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
<u>almonds</u>	<u>0.05</u>

PROPOSED U.S. TOLERANCES:Petition No. 9F3740RCB Reviewer NelsonResidue: per 180.434

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
<u>almonds</u>	<u>0.1</u>
<u>almond hulls</u>	<u>0.1</u>

CANADIAN LIMITS:☒ No Canadian limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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MEXICAN LIMITS:☒ No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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NOTES:

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END OF DOCUMENT

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R062835

Chemical:	Propiconazole
PC Code:	122101
HED File Code	11500 Petition Files Chemistry
Memo Date:	08/05/2003 12:00:00 AM
File ID:	DPD229723; DPD229114; DPD234297
Accession Number:	412-04-0144

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06/29/2004

