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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

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

MEMORANDUM

DATE: 15-AUG-2002

SUBJECT: PP#6F03454. Bifenthrin On Pear and Nut, Tree, Group. **Evaluation of Residue Data and Analytical Methods.** MRID#s 45377301-45377305. Chemical 128825. Barcodes D274839 and D280288. Case 240678. Submission S597032 and S607831.

FROM: Sarah J. Levy, Chemist *Sarah J. Levy*
George F. Kramer, Ph.D., Chemist
Registration Action Branch 1 (RAB 1)
Health Effects Division (HED) (7509C)

THRU: G. Jeffrey Herndon, Branch Senior Scientist *G. Jeffrey Herndon*
RAB1/HED (7509C)

TO: George LaRocca, PM Team 13
Insecticide Branch
Registration Division (RD) (7505C)

FMC Corporation has submitted an amendment to PP#6F03454, which requested the establishment of tolerances for residues of the insecticide bifenthrin [(2-methyl[1,1-biphenyl]3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropanecarboxylate] in/on strawberries, pears, walnuts, and pecans at 3.0, 1.0, 0.05, and 0.05 ppm, respectively. The amendment consists of a revised Section B, additional residue chemistry data, and a revised Section F. The petitioner is now proposing the establishment of tolerances for residues of bifenthrin in/on the following raw agricultural commodities (RACs):

- Pears 1.0 ppm
- Tree nuts 0.05 ppm
- Almond hulls 2 ppm

The attached contractor's document has been reviewed and revised to reflect current HED policy.

Executive Summary of Chemistry Deficiencies

- Revised Section B.
- Revised Section F.
- Revisions to analytical method P-2763.

RECOMMENDATIONS

Provided that Section's B and F are revised, HED concludes that adequate data are available to support the proposed uses on pear and the nut, tree, group. However, registration should be made conditional until revisions to analytical method P-2763 are accepted.

HED notes that tolerances have been proposed for residues of bifenthrin in/on filberts and pistachios at 0.05 ppm (PP#2F04139; DP Barcode D182003, 18-OCT-1993, G. Kramer); this petition is currently in reject status pending submission of a revised Section B and resolution of the issues pertaining to the walnut enforcement method. With proposal of a nut, tree, group tolerance, a tolerance for filberts will not be needed.

A risk assessment will be conducted for pears and tree nuts in conjunction with the bifenthrin Tolerance Reassessment Eligibility Decision (TRED) (currently in preparation).

Attachment 1 - contractor review
Attachment 2 - 45377301.der.wpd
Attachment 3 - 45377302.der.wpd
Attachment 4 - 45377304.der.wpd
Attachment 5 - 45377305.der.wpd

cc: G. Kramer, S. Levy
RDI: G. Herndon (15-AUG-2002), RAB1 Chemists (01-AUG-2002)
G.F. Kramer:806T:CM#2:(703)305-5079:7509C:RAB1

BIFENTHRIN
PC Code 128825
(DP Barcodes D274839 and D280288)

PP#6F03454: Supplemental Residue Chemistry Data
To Support Permanent Tolerances For Use Of Bifenthrin
On Pears And Tree Nuts

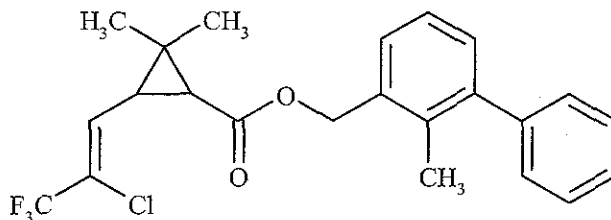
February 4, 2002

Contract No. 68-W-99-053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
20440 Century Boulevard, Suite 100
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BIFENTHRIN



PP#6F03454: SUPPLEMENTAL RESIDUE CHEMISTRY DATA TO SUPPORT PERMANENT
TOLERANCES FOR USE OF BIFENTHRIN ON PEARS AND TREE NUTS

PC Code 128825

(DP BARCODES D274839 & D280288)

INTRODUCTION

FMC Corporation has submitted an amendment to PP#6F3454, which requested the establishment of tolerances for residues of the insecticide bifenthrin *per se* in/on strawberries, pears, walnuts, and pecans at 3.0, 1.0, 0.05, and 0.05 ppm, respectively. The amendment consists of a revised Section B, additional residue chemistry data, and a revised Section F. The petitioner is now proposing the establishment of tolerances for residues of bifenthrin in/on the following RACs:

Pears	1.0 ppm
Tree nuts	0.05 ppm
Almond hulls	2 ppm

Previously, HED had concluded that submission of a revised Section B and modification of the proposed enforcement method for walnuts were required before HED could recommend for the establishment of the proposed tolerances (DP Barcode D184317, 09-MAR-1994, J. Morales and DP Barcode D208420, 19-OCT-1994, J. Morales). The petitioner later requested that the strawberry tolerance petition be separated from the petition for pear, pecan, and walnut tolerances (PP#5F4485; DP Barcodes D213052 and D213794, 25-JAN-1996, J. Morales); the tolerance for strawberries has since been established.

Tolerances are currently established for residues of bifenthrin *per se* in/on several plant and livestock commodities [40 CFR §180.442(a)]. In addition, time-limited tolerances for residues of bifenthrin have been established for certain plant commodities in support of Section 18 Emergency Exemptions [40 CFR §180.442(b)].

The Residue Chemistry Chapter of the Bifenthrin Tolerance Reassessment Eligibility Decision (TRED) is currently in preparation (DP Barcode D283808, S. Levy).

CONCLUSIONS/RECOMMENDATIONS

Provided that the Sections B and F are revised, HED concludes that adequate data are available to support the proposed uses on pear and the nut, tree, group. However, revisions to analytical enforcement method P-2763 are required.

HED notes that tolerances have been proposed for residues of bifenthrin in/on filberts and pistachios at 0.05 ppm (PP#2F04139; DP Barcode D182003, 18-OCT-1993, G. Kramer); this petition is currently in reject status pending submission of a revised Section B and resolution of the issues pertaining to the walnut enforcement method. With proposal of a nut, tree, group tolerance, a tolerance for filberts will not be needed.

A risk assessment will be conducted for leaf petioles subgroup 4B in conjunction with the bifenthrin TRED (currently in preparation).

DATA SUMMARY**OPPTS GLN 860.1200: Proposed Uses**

FMC has submitted a revised Section B, which includes revised use directions for pears, pecans, and walnuts. HED notes that proposed uses for almonds or the tree nut crop group were not included on the submitted specimen labels. The 10% wettable-powder (WP) formulation (Brigade® WSB Insecticide/Miticide; EPA Reg. No. 279-3108) and the 2 lb/gal emulsifiable concentrate (EC) formulation (Capture 2EC Insecticide/Miticide; EPA Reg. No. 279-3069) are proposed for use on pears, pecans, and walnuts.

The 10% WP and 2 lb/gal EC formulations are proposed for multiple foliar applications to pears at 0.04-0.2 lb ai/A/application, using a minimum 30-day retreatment interval (RTI). A maximum seasonal rate of 0.5 lb ai/A, with no more than 0.45 lb ai/A applied after petal fall, is proposed. Applications may be made using ground equipment as a full cover dilute spray in a minimum of 400 gal/A of water. Aerial applications may be made in a minimum of 10 GPA. The proposed pre-harvest interval (PHI) is 14 days and the grazing of livestock or feeding of treated cover crops is prohibited.

The 10% WP and 2 lb/gal EC formulations are proposed for multiple foliar applications to pecans at 0.05-0.2 lb ai/A/application, using a minimum 15-day RTI. The proposed labels currently state that "up to 0.50 lb ai may be applied up to shuck split." A 21-day PHI is proposed. Dilute applications may be made using ground equipment to the point of drip in a minimum of 100 gal/A for smaller trees or 300 gal/A for larger trees. Aerial applications may be made in a minimum of 15 gal/A. The grazing of livestock or feeding of treated cover crops is prohibited.

The 10% WP and 2 lb/gal EC formulations are proposed for multiple foliar applications to walnuts at 0.04-0.2 lb ai/A/application, using a minimum 25-day RTI. A maximum seasonal rate of 0.50 lb ai/A is proposed. The proposed PHI is 7 days for walnuts. Applications may be made using ground equipment in a minimum of 100 gal/A (concentrate sprays) or 200 gal/A (dilute sprays). Aerial applications may be made in a minimum of 20 gal/A. The grazing of livestock or feeding of treated cover crops is prohibited.

Comments: The most recent review for PP#6F03454 (DP Barcode D184317, 09-MAR-1994, J. Morales) concluded that a revised Section B was required to include a 21-day PHI and a minimum spray volume of

300 gal/A for application of the 10% WP formulation to pecans. These modifications have been made to the proposed label. Although the petitioner has maintained a minimum spray volume of 100 gal/A for smaller trees, HED concludes that additional field trial data will not be required to support this spray volume; under current OPPTS guidelines, a spray volume of 100 gal/A is considered to be a dilute spray. However, the proposed use directions for pecans should now be modified to clarify that the maximum application rate is 0.5 lb ai/A and that this is the maximum application rate per growing season.

The petitioner has not included any proposed use directions for bifenthrin on almonds. Before the submitted crop field trial data for almonds can be evaluated, the petitioner should propose a use for the 10% WP formulation of bifenthrin on almonds.

The petitioner has now proposed the use of the 2 lb/gal EC formulation on pears, pecans, and walnuts. No crop field trial data reflecting application of the 2 lb/gal EC formulation to pears, pecans, or walnuts have been submitted previously. Because the proposed uses of bifenthrin are foliar applications, field trial data cannot be translated among the WP and EC formulation classes. Therefore, if the petitioner wishes to register the EC formulation for use on pears, pecans, or walnuts, crop field trial data reflecting application of the EC formulation at the maximum proposed application rates should be submitted. The petitioner should consult OPPTS 860.1500 for guidance on the number of field trials to conduct to support registration of a second formulation.

OPPTS GLN 860.1300: Nature of the Residue - Plants and Livestock

The nature of the residue in plants is adequately understood based on plant metabolism studies on corn, cotton, and apple (in conjunction with PP#7F3546, PP#6F3454, and PP#7F3546, respectively). HED previously determined that for purposes of tolerance expression and risk assessment, the residue of concern in cotton and apple commodities is bifenthrin *per se* (see Memos of M. Flood, 24-DEC-1987; N. Dodd, 02-JUL-1987; and M. Flood, 24-DEC-1987). The HED Metabolism Committee in 1993 re-examined the cotton and apple metabolism data and examined additional corn metabolism data; the Committee determined that the residue of concern in plant commodities is bifenthrin *per se* (Memo, M. Flood, 23-JUL-1993).

The nature of the residue in livestock is adequately understood based on goat and hen metabolism studies. The HED Metabolism Committee determined that for purposes of tolerance expression and risk assessment, the residue of concern in livestock is bifenthrin *per se* (Memo, M. Flood, 23-JUL-1993).

OPPTS GLN 860.1340: Residue Analytical Method - Plants

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The petitioner has previously submitted enforcement methods for pears (FMC Method P-0757) and pecans (FMC Method PC-0130) which have undergone successful petition method validation (PMV) at EPA's Analytical Chemistry Laboratory (ACL). The general procedures of these methods involve extraction of the sample with acetone, partitioning with hexane, purification of the extract by Florisil column chromatography, and analysis of the extract by gas chromatography (GC)/electron-capture detector (ECD). The limit of quantitation (LOQ) for these methods is 0.05 ppm.

Method P-0130 was also proposed for the enforcement of the proposed walnut tolerance. However, the PMV of Method P-0130 was unsuccessful for walnuts. The method for walnuts was required to be

modified to improve sample extract cleanup (to remove compounds that affected the GC column and detector performance); some additional editorial modifications were also required (PP#6F3454; DP Barcode D208420, 19-OCT-1994, J. Morales).

The petitioner has now submitted a GC/ECD method, P-2763 (MRID 45377301), for the quantitation of bifenthrin residues in/on walnuts, peanuts, and peanut processed commodities. The method was originally developed for peanut processed commodities, and is a modification of Method PC-0130.

Based on the submitted method validation recoveries, GC/ECD Method P-2763 adequately recovers residues of bifenthrin from walnut nutmeats, peanut nutmeats, and peanut processed commodities. This method was found to give acceptable recoveries ranging 79-105% ($96 \pm 9.1\%$) for the analysis of peanut nutmeats fortified with bifenthrin at 0.05-0.5 ppm, 85-113% ($101 \pm 9.5\%$) for the analysis of walnut nutmeats fortified at 0.05-0.2 ppm, and 83-94% ($86 \pm 4\%$) for the analysis of peanut soapstock and crude and refined oil. Representative chromatograms demonstrated good peak shape and based on these chromatograms and nondetectable levels of bifenthrin in untreated samples of peanut commodities and walnut nutmeat samples, there appear to be no matrix interferences.

Because the method has not been significantly modified from the previously submitted method, a new independent laboratory validation (ILV) will not be required for walnuts.

The method limit of detection (LOD) and LOQ for bifenthrin were reported at 0.01 and 0.05 mg/kg, respectively. The standard deviations measured with respect to recoveries following spiking at the LOQ appear to be indicative of the method having good repeatability in peanut commodities and walnut nutmeat.

The submitted modified GC/ECD method is similar to the GC/ECD enforcement methods available for cottonseed, pears, corn commodities, and pecans; therefore additional radiovalidation data are not required.

Comments: The development of this analytical method is classified acceptable to satisfy the analytical method data requirements (Residue Chemistry Guidelines OPPTS 860.1340). However, the method should be rewritten prior to submission to ACL for PMV. The petitioner should submit a revision of this method such that it includes a stepwise description of the analytical procedure with sufficient detail to enable competent analysts to apply the method even though they are unfamiliar with the procedure. The method write-up should be in the present tense. HED notes that these editorial recommendations were made by ACL after the unsuccessful PMV of the original method for walnuts. In addition, the following modifications should be made: (i) the title for the "Soapstock" extraction procedures should be modified to state "Walnut nutmeats, peanut nutmeats, and peanut soapstock" (the petitioner may wish to remove soapstock from the method as EPA no longer requires residue data for peanut soapstock); and (ii) the solvent used to adjust the final extract to volume for GC analysis should be specified.

Samples from the almond and pear field trial and pear processing studies reviewed herein were analyzed for residues of bifenthrin using GC/ECD Method P-2792 (pears), or GC/mass-selective detector (MSD) Method P-2763 (almond nutmeats and hulls) or modified Method P-2792 (processed pear commodities). These methods are modifications of the tolerance enforcement methods. HED notes that the almond method is the same as the modified method submitted for walnuts, but utilizes GC/MSD instead of GC/ECD. The reported LOQs for these methods are 0.05 ppm each in/on almond nutmeats and hulls, and

pears, and 0.01 ppm in processed pear commodities. Adequate concurrent method recovery data have been submitted for these methods for data collection purposes.

OPPTS GLN 860.1340: Analytical Methods - Livestock

Almond hulls are the only livestockfeed commodity resulting from the proposed uses of bifenthrin on pears and tree nuts; there are no poultry feed items resulting from the proposed use. Adequate methods are available for the analysis of bifenthrin in ruminant commodities. FMC Method P-1031 is available for enforcement of tolerances for bifenthrin residues in milk and ruminant tissues; the LOQ is 0.05 ppm.

OPPTS GLN 860.1360: Multiresidue Method

The Food and Drug Administration (FDA) PESTDATA database dated 10/99 (PAM Vol. I, Appendix II) indicates that bifenthrin is completely recovered using Multiresidue Methods Section 303 (Mills, Onley, and Gaither; Protocol E, nonfatty) and that recoveries using Section 302 (Luke Method; Protocol D) are variable. No information for recovery of bifenthrin using Section 304 (Mills, fatty food) is available.

OPPTS GLN 860.1380: Storage Stability Data

As summarized in the Residue Chemistry Chapter of the Bifenthrin TRED (Memo, S. Levy, currently under review, D283808), previously submitted storage stability data indicate that residues of bifenthrin are stable during frozen storage for up to: 12 months in corn flour, meal, oil, and starch; 18 months in/on oranges (whole) and orange dried pulp, juice, and oil; 24 months in/on cottonseed; 34 months in/on corn grain; 36 months in/on lettuce, pecans, and potatoes; and 49 months in/on apple, corn silage, and corn stover.

Maximum storage intervals of field trial samples prior to analysis for bifenthrin were 314 days (~10 months) for pears and 125 days (~4 months) for almond nutmeats and hulls. The maximum storage interval for pear RAC and its processed commodities from the processing study was 583 days (~19 months). The available storage stability data on pecans, apples, and orange processed commodities support the storage intervals and conditions of samples from the almond and pear field trials and the pear processing study.

OPPTS GLN 860.1500: Magnitude of the Residue - Plants

In support of the proposed tolerances and uses for bifenthrin 10% WP formulation on pears and tree nuts, FMC has submitted data from crop field trials on almonds (MRID 45377305) and pears (MRIDs 45377302 and 45377303). Previously submitted field trial data were considered adequate to support the proposed uses of the 10% WP formulation on pears, pecans, and walnuts. Almond field trial data have been submitted to support the proposed tree nut crop group tolerance and pear field trial data have been submitted in support of adding lower spray volumes to the proposed use.

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Pears: FMC has submitted two studies (MRIDs 45377302 and 45377303) depicting the magnitude of bifenthrin residues in/on pears reflecting the use of a WP formulation (Brigade® WSB Insecticide/Miticide; 10% WP; EPA Reg. No. 279-3108) using two different spray volumes, ~400 GPA, as specified on the proposed label, and ~50 GPA.

The results from the crop field trial studies in pears have shown that residues of bifenthrin ranged 0.10-0.38 ppm in/on pears harvested 14 days following the last of three foliar applications of the 10% WP formulation of bifenthrin at 0.1, 0.2, and 0.2 lb ai/A in a spray volume of ~400 GPA for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate for pears). In side-by-side trials in which pears were treated at the same rate but with a spray volume of ~50 GPA, residues of bifenthrin ranged 0.12-0.43 ppm.

Comments: The submitted pear field trial data are classified as acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500) in conjunction with previously submitted pear field trial data. However, the field trial data are not sufficient to support the petitioner's request to add lower spray volumes to the proposed label for pears. Furthermore, the petitioner should submit a revised Section F for "pear" at 0.50 ppm.

The proposed 10% WP label specifies that ground applications be made in a minimum of 400 GPA. The petitioner concluded that because the maximum residues observed in/on pears treated using a reduced 50 GPA spray volume (0.43 ppm) were only slightly higher than in/on pears treated using a 400 GPA spray volume (0.38 ppm), the lower spray volume could be added to the proposed label. HED concludes that the submitted data are insufficient to allow HED to conclude that use of a concentrate spray volume will not result in increased residues in/on pears. In each of the three side-by-side trials conducted, residues in/on pears were higher with the 50 GPA spray volume than with the 400 GPA spray volume.

The OPPTS 860.1500 guidelines specify that a request to add another type of spray to a label requires a reduced number of field trials. To support the addition of concentrate spray volumes to the proposed label for pears, a minimum of 6 field trials is required; only three field trials with the concentrate spray volume have been conducted. Therefore, if the petitioner wishes to add concentrate spray volumes to the label for the 10% WP formulation, three additional crop field trials with pears utilizing a concentrate spray volume would be required. Alternatively, the petitioner may simply retain the minimum 400 GPA spray volume on the proposed label and no additional data will be required for pears.

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Tree nuts: FMC has submitted a study (MRID 35377305) depicting the magnitude of bifenthrin residues in/on almonds reflecting the use of a WP formulation (Brigade® WSB Insecticide/Miticide; 10% WP; EPA Reg. No. 279-3108). FMC's submission is in support of an amended Section 3 registration for use of the Brigade WSB on the tree nuts crop group (Crop Group 14). However, the administrative materials of the petition did not include specimen labels with proposed uses for almonds or the tree nuts group (the specimen labels included in the submission did contain proposed uses on pecans and walnuts). The representative crops of the tree nuts group are almonds and pecans.

The results from the crop field trial studies in almonds have shown that residues of bifenthrin were less than the method LOQ (<0.05 ppm) in/on almond nutmeats and ranged 0.84-1.97 ppm in/on almond hulls harvested 7 days following the last of five applications, two soil-directed and three foliar, of the 10% WP formulation of bifenthrin at 0.2 (soil) or 0.1 (foliar) lb ai/A/application for a total rate of 0.7 lb ai/A. The following application pattern was used: a single soil application, followed by a foliar application 0-20 days later, followed by a soil application at hull split, 63-93 days following the second application, followed within 1 day by a foliar application, followed by a foliar application 7-8 days later. The treatment scheme used in the field trials cannot be compared to the proposed use rate because the petitioner has not proposed a use pattern for almonds. The mean field trial residue (FTMaR) of bifenthrin in/on the samples treated at 0.7 lb ai/A was <0.05 ppm for nutmeats and 1.47 ppm for almond hulls. In a

trial where treatments were made at half the target rate, residues of bifenthrin were below the method LOQ in/on almond nutmeats and 0.74-0.83 ppm in/on almond hulls harvested 6 days following the last of five applications (two soil and three foliar applications) of the 10% WP formulation of bifenthrin at 0.1 (soil) or 0.05 (foliar) lb ai/A/application for a total rate of 0.35 lb ai/A.

Comments: The submitted almond field trial data are classified as acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500). Although the required number of field trials were conducted (total of five trials) to support a tree nut crop group tolerance, one trial was conducted at half the target rate because of calculation errors; therefore, only four field trials are representative of the target application rate. However, because the residue levels were consistent among the four field trials, HED is not asking for an additional field trial. In addition, if the petitioner wishes to register the EC formulation for use on almonds, crop field trial reflecting application of the EC formulation to almonds should be submitted. However, a revised Section B should be submitted for almonds which matches the crop field trial use pattern.

Previously-Submitted Tree Nut Data

Walnut: FMC submitted walnut field trial data that were previously reviewed (Memo, J. Morales, 09-MAR-1994; D184317). Two trials were conducted during 1990 in California (MRID# 42515603). Ground foliar application was made in one trial and aerial foliar application was made in the other trial. Four applications were made with 23- to 63-day intervals between applications and the rate of each application was 0.2 lbs. ai/A. Control and treated walnut samples were collected 7 days after the last application. After pesticide application, samples were shipped frozen to the Residue Chemistry Department, FMC Corporation, Princeton, NJ for residue analysis. In the Residue Chemistry Department, the samples were stored frozen at -18°C until analysis. Walnut samples were analyzed for bifenthrin residues up to almost 5 months after sampling. Maximum interval between extraction and analysis was 1 day. The LOQ of the analytical method was 0.05 ppm. The LOD of the method was 0.01 ppm. Control and recoveries were analyzed along with the walnut samples. Control values were <0.01 ppm. Recoveries at a fortification level of 0.05 ppm ranged from 65% to 99%. The analytical method was validated by an independent laboratory in FMC Report PC-0130. Residues of bifenthrin in treated walnuts were non-detectable.

Pecan: FMC submitted pecan field trial data that were previously reviewed (PP#6F03454; CB Nos. 6715, 7036-7044, 10-JAN-1991, N. Dodd). Eight residue studies on pecans were conducted in 1987 and 1988 in the states of GA (2), LA (2), and TX (4) (MRID 41492604). Eight applications of Brigade 10 WP were made at the rate of 0.2 lb ai/A. Broadcast applications were made with ground equipment (handgun sprayers, Savage Speed Sprayer, and FMC Orchard Sprayer) in four studies. Aerial applications were made in the other four studies. The PHI was 21 days in all eight of the studies. Samples were frozen between sampling and analysis. Pecan nut meat samples were analyzed within 25 months of sampling. The LOQ of the analytical method was 0.05 ppm. The LOD of the method was 0.01 ppm. Control and recoveries were analyzed along with the pecan nut meat samples in 1987 and 1988. Control values were not detectable (<0.01 ppm). Recoveries at fortifications of 0.05-0.10 ppm were 81-99%. Residues of bifenthrin in pecan nut meat at a 21-day PHI were all not detectable (<0.01 ppm).

Comments: The previously submitted field trial data were considered adequate to support the proposed uses for pecans and walnuts. Almond field trial data have been submitted to support the proposed tree nut crop group tolerance. These data are adequate to support a "nut, tree, group" tolerance of 0.05 ppm; however, the petitioner should submit a revised Section F with the correct commodity definition.

OPPTS GLN 860:1520: Processed Food/Feed*45377304.der.wpd*

FMC has submitted a pear processing study (MRID 45377304) to address dietary issues related to infants and children as impacted by the FQPA. HED does not currently require residue data or tolerances for pear processed commodities; however, the submitted data may be used for risk assessment purposes.

In the pear processing study, the 10% WSB formulation of bifenthrin was applied to pears three times at 0.1-0.3 lb ai/A/application for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate). Detectable residues of bifenthrin were observed at 0.359 and 0.731 ppm in unwashed pear RAC from the processor. The pear was processed according to simulated commercial procedures into washed pear, mechanically peeled canned pear, and mechanically peeled or unpeeled wet pomace, puree, and nectar. Analysis of the processed pear fractions indicated that residues of bifenthrin reduce or do not concentrate in washed pears (0.3x), and canned pears, puree, and nectar (each <0.1x). Residues of bifenthrin did however concentrate in wet pomace from peeled pears (3.3x) and wet pomace from unpeeled pears (17x).

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

Almond hulls are the only livestock feed commodity resulting from the proposed uses on tree nuts and pears; almond hulls are only a feed commodity for ruminants. Almond hulls are not expected to have a significant impact on the maximum theoretical dietary burden (MTDB) (as calculated in the Residue Chemistry Chapter of the Bifenthrin TRED, S. Levy, currently under review; D283838) for beef and dairy cattle when compared to the existing exposure from registered uses on corn and cottonseed. HED concludes that the current tolerances on meat and milk are adequate to cover the added residues resulting from proposed uses on almonds. Tolerances have been established for residues of bifenthrin *per se* in milk (1.0 ppm in milk fat reflecting 0.1 ppm in whole milk), animal fat (1.0 ppm), meat (0.5 ppm), and meat by-products (0.10 ppm).

OPPTS GLN 860.1850: Confined/Field Accumulation in Rotational Crops

Pears and tree nuts are not rotatable crops; therefore, the confined and field accumulation of bifenthrin residues in rotational crops are not required to support the subject petition.

Other Considerations:

As there are no Mexican, Canadian or Codex maximum residue limits (MRLs) established for bifenthrin in/on tree nuts there are no compatibility issues to be reconciled for any proposed U.S. tree nut tolerance. There are no Mexican or Canadian MRLs established for bifenthrin for pears, however, a Codex MRL has been established for residues of bifenthrin in/on pears at 0.5 ppm. The proposed tolerance expression for pears is compatible with Codex, but the proposed U.S. tolerance is twice the Codex MRL. An International Residue Limits Status (IRLS) sheet is attached.

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: (2-methyl[1,1-biphenyl]3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropane carboxylate	Common Name: Bifenthrin	<input checked="" type="checkbox"/> Proposed tolerance <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	Date: 12/01
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
<input type="checkbox"/> No Codex proposal step 6 or above <input type="checkbox"/> No Codex proposal step 6 or above for the crops requested		Petition Number: PP#6F03454 DP Barcode: D274839 Other Identifier:	
Residue definition (step 8/CXL): Bifenthrin		Reviewer/Branch: RAB1	
		Residue definition: Bifenthrin <i>per se</i>	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
Pears	0.5	Pears	1.0
		Tree nuts	?
		Almond hulls	?
Limits for Canada		Limits for Mexico	
<input checked="" type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested		<input type="checkbox"/> No Limits <input checked="" type="checkbox"/> No Limits for the crops requested	
Residue definition: N/A		Residue definition: Bifentrina	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
Notes/Special Instructions: S. Funk 11/01			

Rev. 1998

Chemical Name Bifenthrin
 PC Code: 128825
 EPA Barcode: D274839, D280288

Residue Analytical Method
 GL: OPPTS 860.1340
 PP#6F03454

MRID: 45377301
 Case No.: 240678
 Submission: S597032, S607831



EPA Reviewer: Saul Levy, Date 8/14/12

STUDY TYPE: Residue Analytical Method; OPPTS 860.1340

TEST MATERIAL: Bifenthrin; PC Code 128825; CAS No. 82657-04-3

SYNONYMS: FMC 54800; Capture®; Brigade®; Talstar®

CITATION: 45377301 Chen, A. (1999) Residue Analytical Method for the Determination of Bifenthrin in/on Walnut, Peanut, and Peanut Processed Parts: Lab Project Number: 182MDV92R1: P-2763. Unpublished study prepared by FMC Corp. 44 p.

SPONSOR: FMC Corporation

EXECUTIVE SUMMARY:

A. Methods for Residue Analysis of Plants - MRID 45377301

The nature of the residue in plants is adequately understood based on plant metabolism studies on corn, cotton, and apple (in conjunction with PP#7F3546, PP#6F3454, and PP#7F3546, respectively). HED previously determined that for purposes of tolerance expression and risk assessment, the residue of concern in cotton and apple commodities is bifenthrin *per se* (see Memos of M. Flood, 24-DEC-1987; N. Dodd, 02-JUL-1987; and M. Flood, 24-DEC-1987). The HED Metabolism Committee in 1993 re-examined the cotton and apple metabolism data and examined additional corn metabolism data; the Committee determined that the residue of concern in plant commodities is bifenthrin *per se* (Memo, M. Flood, 23-JUL-1993).

The nature of the residue in livestock is adequately understood based on goat and hen metabolism studies. The HED Metabolism Committee determined that for purposes of tolerance expression and risk assessment, the residue of concern in livestock is bifenthrin *per se* (Memo, M. Flood, 23-JUL-1993).

The petitioner has submitted a gas chromatography (GC)/electron-capture detector (ECD) method, P-2763, for the quantitation of bifenthrin residues in/on walnuts, peanuts, and peanut processed commodities. The method was originally developed for peanut processed commodities, and is a modification of the method PC-0130 that has been previously proposed for the enforcement of proposed tolerances for pecans and walnuts (PP#6F3454; CB Nos. 6715 and 7036-7044, 10-JAN-1991, N. Dodd). A petition method validation (PMV) was previously conducted for pecans and walnuts using method PC-0130; the PMV was successful for pecans but unsuccessful for walnuts. The Analytical Chemistry Laboratory (ACL) required that the method be modified to improve sample extract cleanup (to remove compounds that affected the GC column and detector performance); some additional editorial modifications were also required (PP#6F3454; DP Barcode D208420, 19-OCT-1994, J. Morales).

Chemical Name Bifenthrin
PC Code: 128825
EPA Barcode: D274839, D280288

Residue Analytical Method
GL: OPPTS 860.1340
PP#6F03454

MRID: 45377301
Case No.: 240678
Submission: S597032, S607831

Based on the submitted method validation recoveries, the modified GC/ECD method adequately recovers residues of bifenthrin from walnut nutmeats, peanut nutmeats, and peanut processed commodities. This method was found to give acceptable recoveries ranging 79-105% ($96 \pm 9.1\%$) for the analysis of peanut nutmeats fortified with bifenthrin at 0.05-0.5 ppm, 85-113% ($101 \pm 9.5\%$) for the analysis of walnut nutmeats fortified at 0.05-0.2 ppm, and 83-94% ($86 \pm 4\%$) for the analysis of peanut soapstock and crude and refined oil. Representative chromatograms demonstrated good peak shape and based on these chromatograms and nondetectable levels of bifenthrin in untreated samples of peanut commodities and walnut nutmeat samples, there appear to be no matrix interferences.

Because the method has not been significantly modified from the previously submitted method, a new independent laboratory validation (ILV) will not be required for walnuts.

The method limit of detection (LOD) and limit of quantitation (LOQ) for bifenthrin were reported at 0.01 and 0.05 ppm, respectively. The standard deviations measured with respect to recoveries following spiking at the LOQ appear to be indicative of the method having good repeatability in peanut commodities and walnut nutmeat.

The submitted GC/ECD method is similar to the GC/ECD enforcement methods available for cottonseed, pears, corn commodities, and pecans; therefore additional radiovalidation data are not required.

The development of this analytical method is classified acceptable to satisfy the analytical method data requirements (Residue Chemistry Guidelines OPPTS 860.1340). However, the method should be rewritten prior to submission to ACL for PMV. The petitioner should submit a revision of this method such that it includes a stepwise description of the analytical procedure with sufficient detail to enable competent analysts to apply the method even though they are unfamiliar with the procedure. The method write-up should be in the present tense. We note that these editorial recommendations were made by ACL after the unsuccessful PMV of the original method for walnuts. In addition, the following modifications should be made: (i) the title for the "Soapstock" extraction procedures should be modified to state "Walnut nutmeats, peanut nutmeats, and peanut soapstock" (the petitioner may wish to remove soapstock from the method as EPA no longer requires residue data for peanut soapstock); and (ii) the solvent used to adjust the final extract to volume for GC analysis should be specified.

B. Methods for Residue Analysis of Livestock - An analytical method concerning livestock commodities was not submitted in conjunction with this petition; however a GC/ECD enforcement method (P-1031) is available for ruminant commodities.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. The petitioner stated that submitted study was conducted for method development and, therefore, not conducted in compliance with GLP standards set forth under 40 CFR.

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I. DATA COLLECTION METHODS

PLANTS

Principle of the Method

The petitioner has submitted a GC/ECD method, P-2763, for the quantitation of bifenthrin residues in/on walnuts, peanuts, and peanut processed commodities. The method was originally developed for peanut processed commodities, and is a modification of the method (PC-0130) that has been previously submitted for the enforcement of proposed tolerances for pecans and walnuts. Briefly, residues in/on walnuts, peanuts, and peanut soapstock are extracted (2x) with acetone, filtered, and concentrated. The oily extract is transferred to a centrifuge tube using acetonitrile (ACN) and a small amount of cyclohexane. The mixture is centrifuged and the supernatant (ACN layer) transferred to a separatory funnel containing a 5% NaCl solution. Additional ACN is added to the remaining oily substance and the mixture centrifuged again; the ACN supernatant is added to the separatory funnel containing the initial ACN supernatant and NaCl solution. The supernatants are then partitioned (2x) with cyclohexane. The cyclohexane phases are combined, concentrated in a water bath at ~35 C under a stream of nitrogen, and applied to a silica solid phase extraction (SPE) cartridge for cleanup. Residues are eluted with 2.5% ethyl acetate in hexane, concentrated on a nitrogen evaporator, and adjusted to volume (solvent unspecified) for analysis. Residues of bifenthrin are determined by GC analysis utilizing ECD and an external standard linear calibration.

Residues in/on peanut crude and refined oil are extracted (2x) by centrifugation with ACN. The combined ACN phases are transferred to a separatory funnel containing 5% NaCl solution, and then partitioned with cyclohexane, cleaned up by silica SPE, and analyzed by GC/ECD as described above.

Stability of the primary and/or secondary standard solution

Standards of bifenthrin were prepared in hexane. Fresh dilute standard solutions were prepared monthly; stock and working standard solutions were stored in volumetric containers in refrigerator/freezer unit (temperatures not specified). The bifenthrin standards were assayed on a "regular" basis for percent purity; the petitioner stated that bifenthrin has a proven pattern of stability.

Qualitative description of the method

The petitioner stated that using the GC/ECD conditions specified in the method, bifenthrin had a retention time of ~8.0 minutes in peanut processed commodities, ~5.7 minutes in peanut nutmeats, and ~6.7 minutes in walnut nutmeats. Good peak shape was observed. Based on the sample chromatograms included in the submission, there appears to be no matrix interferences for walnut nutmeats, peanut nutmeats, peanut soapstock, or peanut refined oil. A peak close to the retention time of bifenthrin was observed in the unfortified crude oil sample. It appears the fortified samples and standard run sample were run consecutively without additional interference; however, the chromatograms were not specifically identified as sequential. Residues of bifenthrin were quantitated by external standard linear calibration.

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Quantitative description of the method

Linearity

The linearity of the method/detector response was not reported for the bifenthrin external standards. Linear regression results were reported for walnut nutmeats only ($r^2 = 0.9995$).

Specificity

No data pertaining to the specificity of this method were included in the submission. The submitted GC/ECD method is similar to the GC/ECD enforcement methods available for cottonseed, pears, corn commodities, and pecans.

LOQ

The validated LOQ for residues of bifenthrin was 0.05 ppm for all walnut and peanut commodities.

LOD

The reported LOD for residues of bifenthrin was 0.01 ppm for all walnut and peanut commodities.

Repeatability/Precision

The relative standard deviations measured with respect to recoveries following spiking at the limit of quantitation (0.05 ppm) were 4% for peanut and walnut nutmeats. The mean relative standard deviation at spiking levels ranging 0.05-0.5 ppm was 9.1% for peanut nutmeat and at spiking levels ranging 0.05-0.2 ppm was 9.5% for walnut nutmeat. The values obtained are indicative of the method having good repeatability.

Recovery Findings

Untreated samples of peanut and walnut nutmeats from 1992 and 1990 field trials and untreated samples of peanut soapstock, crude oil, and refined oil, obtained from Texas A&M University, were fortified with bifenthrin standards in hexane at 0.05-0.5 ppm prior to extraction; the hexane was allowed to evaporate at room temperature before proceeding with extraction procedures. Satisfactory recoveries within guideline requirements (70-120%) were obtained from the fortified peanut commodity and walnut nutmeat samples.

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TABLE 1. Recovery Results from Method Validation of Bifenthrin in Peanuts and Walnuts.

Crop matrix	Spiking Level, ppm	Recoveries obtained, %	Range, %	Mean recovery (SD/RSD) ¹
Peanut, nutmeat	0.05	94, 97, 99, 99, 100, 104, 105, 105	94-105	100 (4.0/4.0)
	0.25	79	79	79
	0.5	82	82	82
		n = 10		Overall Mean = 96 (9.1/9.5)
Peanut, soapstock	0.05	83	83	83
	0.25	83	83	83
Peanut, crude oil	0.05	94	94	94
	0.25	84	84	84
Peanut, refined oil	0.05	87	87	87
	0.25	84	84	84
Walnut, nutmeat	0.05	106, 106, 113	106-113	108 (4.0/3.7)
	0.1	85, 103	85-103	94
	0.2	92, 104	92-104	98
		n = 7		Overall Mean = 101 (9.5/9.4)

¹ Standard deviation and relative standard deviation cannot be calculated for less than three values.

Reproducibility

An adequate ILV was previously conducted for pecans and walnuts using the original GC/ECD method PC-0130 submitted for enforcement of proposed tolerances for pecans and walnuts (PP#6F3454; CB Nos. 6715 and 7036-7044, 10-JAN-1991, N. Dodd). A PMV of the method was conducted by ACL, which was successful for pecans but unsuccessful for walnuts. HED required modification of the method for walnuts and noted that if significant modifications were made to the method, a new ILV would be required (PP#6F3454; DP Barcode D208420, 19-OCT-1994, J. Morales). The petitioner stated that the differences between method P-2763 and the previously submitted method (PC-0130) include: (i) use of a 5-gram sample instead of a 20-gram sample for extraction; (ii) two extractions with acetone instead of one; (iii) anhydrous sodium sulfate was not used in the partitioning step and residues were partitioned with cyclohexane instead of hexane; and (iv) a silica SPE cartridge was used instead of a Florisil column for cleanup. These modifications do not require that a new ILV be conducted.

TABLE 2. Recovery Results Obtained by an Independent Laboratory for the Determination of Bifenthrin Residues in Walnut Matrices.

RAC	Spiking Level, ppm	Individual Analysis Levels	Average Recovery, %	Standard Deviation
		Not applicable		

Confirmation of the Identity of the Residues

Extraction efficiency

No radiovalidation data were submitted in conjunction with this petition.

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Method confirmation

The petitioner stated that because the submitted method is based on existing methodology, no additional confirmatory techniques were used.

Optimization of the Analytical Method

The submitted method is a modification of a previously submitted method, optimized to improve cleanup of walnut sample extracts.

Conclusions

The petitioner has submitted a GC/ECD method, P-2763, for the quantitation of bifenthrin residues in/on walnuts, peanuts, and peanut processed commodities. The method was originally developed for peanut processed commodities, and is a modification of the method PC-0130 that has been previously proposed for the enforcement of proposed tolerances for pecans and walnuts (PP#6F3454; CB Nos. 6715 and 7036-7044, 10-JAN-1991, N. Dodd). A PMV was previously conducted for pecans and walnuts using method PC-0130; the PMV was successful for pecans but unsuccessful for walnuts. ACL required that the method be modified to improve sample extract cleanup (to remove compounds that affected the GC column and detector performance); some additional editorial modifications were also required (PP#6F3454; DP Barcode D208420, 19-OCT-1994, J. Morales).

Based on the submitted method validation recoveries, the modified GC/ECD method adequately recovers residues of bifenthrin from walnut nutmeats, peanut nutmeats, and peanut processed commodities. This method was found to give acceptable recoveries ranging 79-105% ($96 \pm 9.1\%$) for the analysis of peanut nutmeats fortified with bifenthrin at 0.05-0.5 ppm, 85-113% ($101 \pm 9.5\%$) for the analysis of walnut nutmeats fortified at 0.05-0.2 ppm, and 83-94% ($86 \pm 4\%$) for the analysis of peanut soapstock and crude and refined oil. Representative chromatograms demonstrated good peak shape and based on these chromatograms and nondetectable levels of bifenthrin in untreated samples of peanut commodities and walnut nutmeat samples, there appear to be no matrix interferences.

Because the method has not been significantly modified from the previously submitted method, a new ILV will not be required for walnuts.

The method LOD and LOQ for bifenthrin were reported at 0.01 and 0.05 ppm, respectively. The standard deviations measured with respect to recoveries following spiking at the LOQ appear to be indicative of the method having good repeatability in peanut commodities and walnut nutmeat.

The submitted modified GC/ECD method is similar to the GC/ECD enforcement methods available for cottonseed, pears, corn commodities, and pecans; therefore additional radiovalidation data are not required.

Deficiencies

The method should be rewritten prior to submission to ACL for PMV. The petitioner should submit a revision of this method which is written as a method (*i.e.*, the method should be written in the present tense and should include the instrument parameters before the data tables and chromatograms; these editorial recommendations were made after the unsuccessful PMV of the original method for walnuts). In addition, the following modifications should be made: (i) the title for the "Soapstock" extraction

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procedures should be modified to state "Walnut nutmeats, peanut nutmeats, and peanut soapstock" (the petitioner may wish to remove soapstock from the method as EPA no longer requires residue data for peanut soapstock); and (ii) the solvent used to adjust the final extract to volume for GC analysis should be specified.

LIVESTOCK

An analytical method concerning livestock commodities was not submitted in conjunction with this petition.

II. OVERALL STUDY DEFICIENCIES

The method should be rewritten prior to submission to ACL for PMV. The petitioner should submit a revision of this method which is written as a method (*i.e.*, the method should be written in the present tense and should include the instrument parameters before the data tables and chromatograms; these editorial recommendations were made after the unsuccessful PMV of the original method for walnuts). In addition, the following modifications should be made: (i) the title for the "Soapstock" extraction procedures should be modified to state "Walnut nutmeats, peanut nutmeats, and peanut soapstock" (the petitioner may wish to remove soapstock from the method as EPA no longer requires residue data for peanut soapstock); and (ii) the solvent used to adjust the final extract to volume for GC analysis should be specified.

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Crop Field Trials
 GL: OPPTS 860.1500
 PP#6F03454

MRID: 45377305
 Case No.: 240678
 Submission: S597032, S607831



EPA Reviewer: Paul Ly, Date 8/14/10

STUDY TYPE: Crop Field Trials - Almond; OPPTS 860.1500

TEST MATERIAL: Bifenthrin; PC Code 128825; CAS No. 82657-04-3

FORMULATION AND TYPE: Brigade® WSB Insecticide/Miticide (10% wettable-powder (WP) formulation in water soluble bag; EPA Reg. No. 279-3108)

SYNONYMS: FMC 54800; Capture®; Brigade®; Talstar®

CITATION: 45377305 Chen, A. (2000) Magnitude of the Residue of Bifenthrin in/on Almonds Treated with Brigade WSB Insecticide-Miticide: Lab Project Number: 182NUT99R1: P-3435. Unpublished study prepared by FMC Corp. 103 p.

SPONSOR: FMC Corporation

EXECUTIVE SUMMARY:

FMC has submitted a study (MRID 45377305) depicting the magnitude of bifenthrin residues in/on almonds reflecting the use of a WP formulation (Brigade® WSB Insecticide/Miticide; 10% WP; EPA Reg. No. 279-3108). FMC's submission is in support of an amended Section 3 registration for use of the Brigade WSB and Capture 2EC products on the tree nuts crop group (Crop Group 14). However, the administrative materials of the petition did not include specimen labels with proposed uses for almonds or the tree nuts group (the specimen labels included in the submission did list proposed uses on pecans and walnuts).

The results from the crop field trial studies in almonds have shown that residues of bifenthrin were less than the method limit of quantitation (LOQ) (<0.05 ppm) in/on almond nutmeats and ranged 0.84-1.97 ppm in/on almond hulls harvested 7 days following the last of five applications, two soil-directed and three foliar, of the 10% WP formulation of bifenthrin at 0.2 (soil) or 0.1 (foliar) lb ai/A/application for a total rate of 0.7 lb ai/A. The following application pattern was used: a single soil application, followed by a foliar application 0-20 days later, followed by a soil application at hull split, 63-93 days following the second application, followed within 1 day by a foliar application, followed by a foliar application 7-8 days later. The treatment scheme used in the field trials cannot be compared to the proposed use rate because the petitioner has not proposed a use pattern for almonds. The mean field trial residue (FTMaR) of bifenthrin in/on the samples treated at 0.7 lb ai/A was <0.05 ppm for nutmeats and 1.47 ppm for almond hulls. In a trial where treatments were made at half the target rate, residues of bifenthrin were below the method LOQ in/on almond nutmeats and 0.74-0.83 ppm in/on almond hulls harvested 6 days following the last of five applications (two soil and three foliar applications) of the 10% WP formulation of bifenthrin at 0.1 (soil) or 0.05 (foliar) lb ai/A/application for a total rate of 0.35 lb ai/A.

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The submitted almond field trial data are classified as acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500). A total of 5 field trials are required for almonds to support a tree nut crop group tolerance. Assuming that the petitioner intends to support a use pattern consisting of two soil applications at 0.2 lb ai/A/application and three foliar applications at 0.1 lb ai/A/application with a maximum seasonal rate of 0.7 lb ai/A and a 7-day PHI, only four field trials reflecting the target use pattern are available. However, because the residue levels were consistent among the four field trials, HED is not asking for an additional field trial. However, a revised Section B should be submitted for almonds which matches the crop field trial use pattern.

If the petitioner wishes to support use of the 2 lb/gal emulsifiable concentrate (EC) formulation on almonds, crop field trial data reflecting application of the EC formulation to almonds at the maximum proposed application rates must be submitted. The petitioner should consult OPPTS 860.1500 for guidance on the number of field trials to conduct to support registration of a second formulation.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. The petitioner that stated supporting data such as soil characteristics, irrigation, and maintenance chemical applications were not collected in strict adherence to 40 CFR 160 guidelines.

I. MATERIALS AND METHODS

Samples of almond nutmeat and hulls were analyzed for residues of bifenthrin using a method P-2763 (see DER for 860.1340; 45377301.der.wpd). The method was modified slightly to use a mass-selective detector (MSD) instead of an electron-capture detector (ECD) for quantitation of residues. Analysis was conducted at FMC Corporation (Princeton, NJ).

Briefly, residues were extracted (2x) with acetone, filtered, and concentrated. The nutmeat extract was centrifuged with acetonitrile (ACN) and a small amount of cyclohexane. The ACN phases were combined and 5% NaCl solution was added. ACN and 5% NaCl solution were added directly to hull sample extracts without centrifugation. Extracts (nutmeat and hulls) were then partitioned (2x) with cyclohexane. The cyclohexane phases were combined, concentrated in a water bath at ~35 C, and applied to a solid phase extraction (SPE) silica cartridge for cleanup. Residues were eluted with 2.5% ethyl acetate in hexane, evaporated to near dryness in a water bath at ~45 C, and redissolved in hexane for analysis. Residue levels of bifenthrin were determined by gas chromatography (GC) analysis utilizing a MSD; external standards were used for quantitation. The reported limit of detection (LOD) and validated LOQ for residues of bifenthrin were 0.01 and 0.05 ppm, respectively, in/on almond nutmeats and hulls. Concurrent method recovery data (presented below under I.4.) were submitted.

Sample chromatograms of control and treated samples were provided; no interference was observed in the regions of bifenthrin in representative chromatograms for control samples. Based on the submitted concurrent recovery data, this method adequately recovers residues of bifenthrin from almond nutmeats and hulls.

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1. Test Compound

Chemical name:

IUPAC: 2-methylbiphenyl-3-ylmethyl (Z)-(1*RS*,3*RS*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

CAS name: (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate

CAS #: 82657-04-3 (cis)

Common name (ANSI, BSI or ISO): Bifenthrin

Developmental (Company) name: FMC 54800

2. Trial Numbers and Locations

Crop/Almonds	U.S. Growing Regions	Total Trials
	10	
Submitted	5	5
Requested ¹	5	5

As per OPPTS 860.1500, Table 5.

Comments: Geographic representation for bifenthrin on almonds is adequate. Although the required number of field trials were conducted, one trial was conducted at half the target rate because of calculation errors; therefore, only four field trials are representative of the target application rate. However, because the residue levels were consistent among the four field trials, HED is not asking for an additional field trial. In addition, if the petitioner wishes to register the EC formulation for use on almonds, crop field trial reflecting application of the EC formulation to almonds must be submitted.

3. Proposed Label Use Pattern

10% WP (EPA Reg. No. 279-3108)

2 lb/gal EC (EPA Reg. No. 279-3069)

Crop	Application					Comments/Restrictions
	Method/ Timing	Rate, lb ai/A	Maximum Number	Total Seasonal Rate, lb ai/A	PHI, days	
Almonds	Not specified					The petitioner has not proposed a use for almonds on the submitted specimen labels.

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4. Analytical Method Validation (Concurrent)

Crop matrix	Spiking Level, ppm	Recoveries obtained, %	Range, %	Mean \pm SD, %
Almond nutmeats	0.05-0.2	91, 95, 102	91-102	96 \pm 5.6
Almond, hulls	0.05-3	88, 104, 106	88-106	99 \pm 9.9

Comments: Based on the concurrent method recoveries, the GC/MSD method is adequate for data collection for residues of bifenthrin in/on almond nutmeats and hulls.

5. Storage Stability Conditions

Commodity	Storage Temperature, °C	Duration, days
Almond nutmeats	-18	90-118
Almond hulls	-18	98-125

Comments: Almonds were separated into nutmeats and hulls and frozen within 6 hours of harvest, except in one field trial where almonds were left on the ground to dry, collected the day after harvest, and separated into nutmeats and hulls prior to being frozen. Samples were shipped frozen within 25 days of harvest to FMC Corporation (Princeton, NJ) where they were stored frozen (-18 C) prior residue analysis. Samples were analyzed within 8 days of extraction. The maximum frozen storage interval from collection to analysis was 125 days (~4 months) for almond nutmeat and hull samples.

Storage stability data have been submitted previously which indicate that residues of bifenthrin are stable for up to 36 months in/on frozen pecans (Residue Chemistry Chapter of the Bifenthrin Tolerance Reassessment Eligibility Decision (TRED), DP Barcode D283808, S. Levy, currently under review). These data are adequate to support the storage conditions and intervals of the almond field trial samples.

6. Application and RAC Information

Five field trials were conducted in CA (EPA Region 10) on almonds during the 1999 growing season; almonds are a representative crop of the tree nut crop group (Crop Group 14). Mature whole almonds were harvested 6-7 days following five applications, two soil applications and three foliar applications, of the 10% WP formulation; soil applications were made at 0.2 lb ai/A/application and foliar applications were made at 0.1 lb ai/A/application. The first application was made to the soil under and around the trees in May; the second application was made foliarly on the same day as the soil application or within 14-20 days of the soil application; the third application was made to the soil at hull split, 63-93 days following the second application; the fourth application was made foliarly within 1 day of the third application; and the fifth (final) application was made foliarly approximately 7 days prior to mature harvest, 7-8 days following the fourth application. Applications were made using ground equipment (handgun or tractor- or ATV-mounted airblast or boom sprayers) in approximately 20 gal/A (GPA) for soil applications and 50-260 GPA (~50 GPA in three trials and 100-260 GPA in two trials) for foliar applications. Applications rates at one field trial were made at half the target rate due to a calculation error. At each site, a separate plot at was not treated to provide control samples. The proposed use pattern for almonds is not available for HED to assess whether the treatment scheme of the field trials reflects the maximum proposed use rate and timing.

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Mature whole almonds were harvested by shaking the trees and collecting the almonds off the ground. A single untreated and duplicate treated samples, each weighing ~10 lbs, were collected at each trial site. At one trial site almonds were left on the ground and collected the next day. Whole almonds were separated into nutmeats and hulls by hand or mechanical huller and cracker at the field site.

7. Site-Specific Information

The soils from the field trials were classified as sandy loam, loam, or clay; no additional soil characteristics were provided. Weather conditions during the field trials were considered normal for the area, and fertilizers and/or maintenance chemicals used at the trial sites are not expected to affect the residue data.

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II. RESULTS

TABLE 1. Residue Data Summary from Crop Field Trials

Location (city, state)/Year	Crop/Variety	Commodity/ Portion analyzed	Formulation	Application				PHI, days	Bifenthrin Residues, ppm ^b	
				Rate, lb ai/A	# of Appl. ^a	Interval Between Apppls.	Total Rate, lb ai/A			Percent of Max. Rate
Lemoore, CA/1999	Almond/ Non-Pareil	Nutmeats	10% WP	0.2 (soil) 0.1 (foliar)	2 soil + 3 foliar	0, 73, 0, 7	0.7	NC ^c	7	(0.01), (0.02) 1.94, 1.97
		Hulls								
Farmersville, CA/ 1999	Almond/ Non-Pareil	Nutmeats	10% WP	0.2 (soil) 0.1 (foliar)	2 soil + 3 foliar	0, 91, 0, 8	0.7	NC	7	<0.01, <0.01 0.84, 0.84
		Hulls								
Porterville, CA/ 1999	Almond/ Non-Pareil	Nutmeats	10% WP	0.2 (soil) 0.1 (foliar)	2 soil + 3 foliar	20, 63, 0, 8	0.7	NC	7	<0.01, <0.01 1.59, 1.64
		Hulls								
Madera, CA/1999	Almond/ Carmels	Nutmeats	10% WP	0.1 (soil) 0.05 (foliar)	2 soil + 3 foliar	14, 90, 1, 8	0.35	NC	6	<0.01, <0.01 0.74, 0.83
		Hulls								
Chico, CA/1999	Almond/ Non-Pareil	Nutmeats	10% WP	0.2 (soil) 0.1 (foliar)	2 soil + 3 foliar	0, 93, 0, 7	0.7	NC	7	<0.01, <0.01 1.43, 1.52
		Hulls								

^a The first application was made to the soil, the second application was made foliarly, the third application was made to the soil (at hull split), and the fourth and fifth applications were made foliarly.

^b Residues estimated between the LOD (0.01 ppm) and LOQ (0.05 ppm) are reported in parentheses.

^c The percent of the maximum rate could not be calculated because the proposed use pattern for almonds or the tree nut crop group was not available.

Apparent residues of bifenthrin were nondetectable (<0.01 ppm) in/on 5 samples each of untreated almond nutmeats and hulls analyzed by GC/MSD.

Chemical Name Bifenthrin
PC Code: 128825
EPA Barcode: D274839, D280288

Crop Field Trials
GL: OPPTS 860.1500
PP#6F03454

MRID: 45377305
Case No.: 240678
Submission: S597032, S607831

Comments:

The submitted almond field trials indicate that residues of bifenthrin were below the method LOQ (<0.05 ppm) in/on almond nutmeats and 0.84-1.97 ppm in/on almond hulls harvested 7 days following the last of five applications (two soil-directed and three foliar applications) of the 10% WP formulation of bifenthrin at 0.2 (soil) or 0.1 (foliar) lb ai/A/application for a total rate of 0.7 lb ai/A. The treatment scheme used in the field trials cannot be compared to the proposed use rate, because the proposed use pattern on almonds has not been identified by the petitioner. The FTMaR of bifenthrin in/on the 0.7 lb ai/A treated samples was <0.05 ppm for nutmeats and 1.47 ppm for almond hulls. In a trial where treatments were made at half the target rate, residues of bifenthrin were below the method LOQ in/on almond nutmeats and 0.74-0.83 ppm in/on almond hulls harvested 6 days following the last of five applications (two soil and three foliar applications) of the 10% WP formulation of bifenthrin at 0.1 (soil) or 0.05 (foliar) lb ai/A/application for a total rate of 0.35 lb ai/A.

III. CONCLUSIONS

The results from the crop field trial studies in almonds have shown that residues of bifenthrin were less than the method LOQ (<0.05 ppm) in/on almond nutmeats and ranged 0.84-1.97 ppm in/on almond hulls harvested 7 days following the last of five applications, two soil-directed and three foliar, of the 10% WP formulation of bifenthrin at 0.2 (soil) or 0.1 (foliar) lb ai/A/application for a total rate of 0.7 lb ai/A. The following application pattern was used: a single soil application, followed by a foliar application 0-20 days later, followed by a soil application at hull split, 63-93 days following the second application, followed within 1 day by a foliar application, followed by a foliar application 7-8 days later. The treatment scheme used in the field trials cannot be compared to the proposed use rate because the petitioner has not proposed a use pattern for almonds. The FTMaR of bifenthrin in/on the samples treated at 0.7 lb ai/A was <0.05 ppm for nutmeats and 1.47 ppm for almond hulls. In a trial where treatments were made at half the target rate, residues of bifenthrin were below the method LOQ in/on almond nutmeats and 0.74-0.83 ppm in/on almond hulls harvested 6 days following the last of five applications (two soil and three foliar applications) of the 10% WP formulation of bifenthrin at 0.1 (soil) or 0.05 (foliar) lb ai/A/application for a total rate of 0.35 lb ai/A.

The submitted almond field trial data are classified as acceptable and satisfies the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500). A total of 5 field trials are required for almonds to support a tree nut crop group tolerance. Assuming that the petitioner intends to support a use pattern consisting for the 10% WP formulation of two soil applications at 0.2 lb ai/A/application and three foliar applications at 0.1 lb ai/A/application with a maximum seasonal rate of 0.7 lb ai/A and a 7-day PHL, only four field trials reflecting the target use pattern are available. However, because the residue levels were consistent among the four field trials, HED is not asking for an additional field trial. However, a revised Section B should be submitted for almonds which matches the crop field trial use pattern.

If the petitioner wishes to support use of the 2 lb/gal EC formulation on almonds, crop field trial data reflecting application of the EC formulation to almonds at the maximum proposed application rates must be submitted. The petitioner should consult OPPTS 860.1500 for guidance on the number of field trials to conduct to support registration of a second formulation.

Chemical Name Bifenthrin
PC Code: 128825
EPA Barcode: D274839, D280288

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IV. STUDY DEFICIENCIES

Geographic representation for bifenthrin on almonds is adequate. Although the required number of field trials were conducted, one trial was conducted at half the target rate because of calculation errors; therefore, only four field trials are representative of the target application rate. However, because the residue levels were consistent among the four field trials, HED is not asking for an additional field trial. In addition, if the petitioner wishes to register the EC formulation for use on almonds, crop field trial reflecting application of the EC formulation to almonds must be submitted.

Chemical Name Bifenthrin
 PC Code: 128825
 EPA Barcode: D274839, D280288

Processed Food/Feed
 GL: OPPTS 860.1520
 PP#6F03454

MRID: 45377304
 Case No.: 240678
 Submission: S597032, S607831



EPA Reviewer: Saul King, Date 8/14/12

STUDY TYPE: Processed Food/Feed Study - Pears; OPPTS 860.1520

TEST MATERIAL: Bifenthrin; PC Code 128825; CAS No. 82657-04-3

FORMULATION AND TYPE: Brigade® WSB Insecticide/Miticide (10% wettable-powder formulation in water soluble bag; EPA Reg. No. 279-3108)

SYNONYMS: FMC 54800; Capture®; Brigade®; Talstar®

CITATION: 45377304 Arabinick, J. (1999) Magnitude of the Residues of Bifenthrin in/on Pears and its Processed Products Following Treatment with Three Applications of Brigade WSB Insecticide-Miticide: Lab Project Number: 182PRS97R2: P-3397. Unpublished study prepared by FMC Corp. 93 p.

SPONSOR: FMC Corporation

EXECUTIVE SUMMARY:

FMC has submitted a pear processing study (MRID 45377304) to address dietary issues related to infants and children as impacted by the Food Quality Protection Act (FQPA) and to support a Section 3 registration of Brigade® WSB Insecticide/Miticide in/on pears. HED does not currently require residue data or tolerances for pear processed commodities; however, the submitted data may be used for risk assessment purposes.

In the pear processing study, the 10% WSB formulation of bifenthrin was applied to pears three times at 0.1-0.3 lb ai/A/application for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate). Detectable residues of bifenthrin were observed at 0.359 and 0.731 ppm in unwashed pear RAC from the processor. The pear was processed according to simulated commercial procedures into washed pear, mechanically peeled canned pear, and mechanically peeled or unpeeled wet pomace, puree, and nectar. Analysis of the processed pear fractions indicated that residues of bifenthrin reduce or do not concentrate in washed pears (0.3x), and canned pears, puree, and nectar (each <0.1x). Residues of bifenthrin did however concentrate in wet pomace from peeled pears (3.3x) and wet pomace from unpeeled pears (17x).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. One GLP deviation (dates of sample homogenization were not recorded) was noted.

Chemical Name Bifenthrin
 PC Code: 128825
 EPA Barcode: D274839, D280288

Processed Food/Feed
 GL: OPPTS 860.1520
 PP#6F03454

MRID: 45377304
 Case No.: 240678
 Submission: S597032, S607831

I. MATERIALS AND METHODS

MATERIALS:

1. Test Compound:

Active ingredient (ai): Bifenthrin

Formulation or spiking substance: 10% WP formulation

Physicochemical Properties: (Bifenthrin Tolerance Reassessment Eligibility Decision (TRED), Product Chemistry Chapter, DP Barcode D283808, S. Levy, currently in preparation)

Physicochemical property	Description
Water solubility (OPPTS 830.7840 and 830.7860)	Practically insoluble in water (<0.1 ppb)
Organic solvent solubility (if available)	Soluble in acetone, chloroform, ether, methylene chloride, and toluene at 125 g/100 mL
n-Octanol/water partition coefficient (Kow) (OPPTS 830.7550)	>1 x 10 ⁶
pKa (OPPTS 830.7370)	Data are not required because the TGAI is practically insoluble in water.
Vapor pressure (OPPTS 830.7950)	1.81 x 10 ⁻⁷ torr at 25 C

2. Test Commodity:

Crop: Pear

Type/Variety: Bartlett

Crop parts used in processing study: Whole pear fruit

Developmental stages (i.e., immature/mature, fresh/dry, etc.):

Application 1: 1.25 inch fruit diameter

Application 2: 1.5 inch fruit diameter

Application 3: 2.5 inch fruit diameter

Harvest: mature fruit

Other: None

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GL: OPPTS 860.1520
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METHODS:

1. Experimental Design:

Method of application: Broadcast foliar spray

Rate of application (comparison to the maximum application rate): A total application of 0.5 lb ai/A (1x the maximum proposed seasonal application rate for pears).

Application rate(s): The first and second applications were made at 0.1 lb ai/A/application and the third application was made at 0.3 lb ai/A.

Number of applications: 3

Number of test/control samples: Samples of raw agricultural commodities (RACs) untreated and treated pears each weighed 9-10 lbs. Bulk pear samples of untreated and treated pears weighed 467 lbs and 519-557 lbs, respectively.

Number of sample replicates: Single untreated samples and duplicate treated samples were collected.

2. Test Procedures:

Manner in which test compound was introduced into RAC: In a single field trial conducted in Royal city, WA in 1997, mature pears were harvested 14 days following the last of three foliar broadcast applications, with 17- and 29-day retreatment intervals, of the 10% WP formulation of bifenthrin at 0.1-0.3 lb ai/A/application for a total rate of 0.5 lb ai/A (1x the proposed seasonal rate). Applications were made in ~50 gal/A of water using ground equipment (tractor-mounted airblast sprayer).

Description of processing procedure and mass balance (include scheme if applicable): Pears were washed and processed by Englar Food Laboratories, Inc. (Moses Lake, WA) into mechanically peeled canned pear, and mechanically peeled or ground (unpeeled) wet pomace, puree, and nectar according to simulated commercial procedures. Briefly, the harvested pears were held at ambient temperature for 3 days and then transferred to cold storage at 7 C to allow the fruit to ripen. Pears were then washed with cold water and an aliquot of washed pear peeled mechanically. An aliquot of peeled pear was sliced and cored by hand, and the pear slices placed in cans, heated syrup added, and the cans sealed and processed in boiling water at 98-100 C for 20 minutes. The remaining peeled pears were processed into puree and nectar by slicing the pears then steaming the pear slices at atmospheric pressure for 10 minutes. The steamed pear slices were then mechanically pulped. Ascorbic acid was added (0.16 g/kg puree) to an aliquot of pear pulp, citric acid was added if necessary to adjust the pH to 3.9-4.1, and the puree mixture was heated to 96-98 C. The processed puree was then put in cans, sealed, and cooled in cold water. To a separate aliquot of pear pulp, water, ascorbic acid, and corn syrup were added and the nectar heated to 96-98 C. The processed nectar was put into cans, sealed, and cooled in cold water. The peel and core waste was chopped in a hammermill and pressed mechanically; the juice was discarded and the wet pomace collected. To generate samples of ground puree, nectar, and wet pomace, unpeeled pears were sliced and processed as above. Flow charts and material balance sheets were included.

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Analytical method: Samples of whole pears (washed and unwashed), wet pomace (peeled and ground), canned pear (peeled), puree (peeled and ground), and nectar (peeled and ground) were analyzed for residues of bifenthrin using a gas chromatography (GC)/mass-selective detector (MSD) method which is a modification of Method P-2792 (used for analysis of samples from the pear field trials in MRIDs 45377302 and 45377303). Analysis was conducted at FMC Corporation (Princeton, NJ). Briefly, residues were extracted (2x) with acetone, centrifuged, and concentrated to aqueous. Water was added and the sample was partitioned (3x) with hexane. The combined hexane extracts were concentrated and applied to a silica solid phase extraction (SPE) cartridge for cleanup. Residues were eluted with 10% ethyl acetate in hexane and concentrated for analysis. Residue levels of bifenthrin were determined by GC analysis utilizing a MSD. This method differs from the enforcement method which used GC/electron-capture detector (ECD) instead of GC/MSD. The reported limit of detection (LOD) and limit of quantitation (LOQ) for residues of bifenthrin were 0.002-0.003 and 0.01 ppm, respectively, in/on pear and its processed commodities. Concurrent method recovery data (presented below under II.1.) were submitted.

Storage stability: Samples of whole pears were delivered under ambient conditions on the same day as harvest to Englar Food Laboratories, Inc. (Moses Lake, WA) for processing. Bulk pear samples were stored at ambient conditions for 3 days and then at ~7 C for ripening prior to processing. Processing was completed within 20 days of harvest and processed samples were then frozen and shipped frozen to FMC Corporation (Richmond, CA). Samples were stored frozen (-18 C) at the Richmond, CA facility until frozen shipment to FMC (Princeton, NJ) where they were stored frozen (-18 C) prior to analysis. Samples of pears and pear processed commodities were stored frozen for 525-583 days (~17-19 months) prior to analysis. Previously submitted storage stability data indicate that residues of bifenthrin are stable in apple, corn silage and corn stover under frozen conditions for 49 months, in cottonseed for 24 months, and in corn grain for 34 months (Bifenthrin TRED, Residue Chemistry Chapter, DP Barcode D283808, S. Levy, currently in preparation). In addition, FMC Corporation has submitted storage stability data for bifenthrin in/on whole oranges and orange dried pulp, juice, and oil demonstrating that bifenthrin is stable for up to 18 months in/on these commodities (MRID 45350911; DP Barcode D274760, S. Levy). These data are adequate to support the storage conditions and intervals of the pear processing samples.

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 Submission: S597032, S607831

II. RESULTS

TABLE 1. Summary of Procedural Recoveries for Pear RAC and Processed Fractions Spiked with Bifenthrin

Crop matrix	Spiking Level, ppm	Recoveries obtained, %	Range, %	Mean recovery, % (SD)
Pear, whole (washed)	12	69	69-129	97 (21)
Canned pears (peeled)	0.01	105		
Puree (peeled)	0.01	107		
Puree (ground)	0.025	77		
Nectar (peeled)	0.01	117		
Nectar (ground)	0.01	78		
Wet pomace (peeled)	0.01	129		
Wet pomace (ground)	0.05	97		

Comments: The recovery data for pears and pear processed commodities indicate that the GC/MS analytical method designed for the determination of bifenthrin residues is adequate for data collection.

TABLE 2. Residue Levels of Bifenthrin in Pear RAC and Processed Fraction

Matrix/Fraction	Total Rate, lb ai/A	PHI, days	Total Residues, ppm ¹	Processing Factor ²
Pear, whole (field)	0.5 (1x)	14	0.654, 0.786 [0.720]	--
Pear, whole, unwashed (processor)	0.5 (1x)	14	0.359, 0.731 [0.545]	--
Pear, whole, washed	0.5 (1x)	14	0.124, 0.215 [0.170]	0.3x
Wet pomace (peeled) ³	0.5 (1x)	14	1.711, 1.841 [1.776]	3.3x
Wet pomace (ground) ⁴	0.5 (1x)	14	7.053, 11.393 [9.223]	17x
Canned pear (peeled)	0.5 (1x)	14	<0.002, (0.003) [<0.003]	<0.1x
Puree (peeled)	0.5 (1x)	14	(0.004), (0.005) [0.005]	<0.1x
Puree (ground)	0.5 (1x)	14	0.011, 0.017 [0.014]	<0.1x
Nectar (peeled)	0.5 (1x)	14	(0.002), (0.003) [0.003]	<0.1x
Nectar (ground)	0.5 (1x)	14	(0.009), 0.012 [0.011]	<0.1x

¹ Residues estimated between the LOD and LOQ are reported in parentheses; average of analyses of duplicate samples reported in brackets.

Chemical Name Bifenthrin	Processed Food/Feed	MRID: 45377304
PC Code: 128825	GL: OPPTS 860.1520	Case No.: 240678
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- ² Processing factors were calculated by the study reviewer using the average residue value for unwashed pear from the processor and the average residue value for each processed commodity.
- ³ Peeled = derived from peeled pears.
- ⁴ Ground = derived from unpeeled pears.

Apparent residues were nondetectable (<0.002 ppm) in/on one sample each of untreated pear (field), unwashed pear (processor), washed pear, canned pear, wet pomace (peeled), wet pomace (ground), puree (peeled), puree (ground), nectar (peeled), and nectar (ground).

Comments: The rate of application (1x) produced quantifiable bifenthrin residues in whole pear RAC (unwashed from the processor). The processing data indicate that residues of bifenthrin reduce or do not concentrate in washed pears (0.3x), and canned pears, puree, and nectar (each <0.1x) processed from pears bearing detectable bifenthrin residues. Residues of bifenthrin did however concentrate in wet pomace from peeled pears (3.3x) and wet pomace from unpeeled pears (17x). HED does not currently require residue data for pear processed commodities; however, the submitted data may be used for risk assessment purposes.

TABLE 3. Concentration Factors, Maximum Residues and Proposed Tolerances for Bifenthrin in Pears and Processed Commodities

RAC	Processed Commodity	Concentration Factor	HAFT/Theoretical Max. Residue, ppm	Proposed Tolerance, ppm
		See Text		

Comments: HED does not currently require residue data or tolerances for pear processed commodities.

III. FINAL SUMMARY

In the pear processing study, the 10% WSB formulation of bifenthrin was applied to pears three times at 0.1-0.3 lb ai/A/application for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate). Detectable residues of bifenthrin were observed at 0.359 and 0.731 ppm in unwashed pear RAC from the processor. The pear was processed according to simulated commercial procedures into washed pear, mechanically peeled canned pear, and mechanically peeled or unpeeled wet pomace, puree, and nectar. Analysis of the processed pear fractions indicated that residues of bifenthrin reduce or do not concentrate in washed pears (0.3x), and canned pears, puree, and nectar (each <0.1x). Residues of bifenthrin did however concentrate in wet pomace from peeled pears (3.3x) and wet pomace from unpeeled pears (17x).

IV. STUDY DEFICIENCIES

No deficiencies were identified.

Chemical Name Bifenthrin
 PC Code: 128825
 EPA Barcodes: D274839, D280288

Crop Field Trials
 GL: OPPTS 860.1500
 PP#6F03454

MRIDs: 45377302, 45377303
 Case No.: 240678
 Submission: S597032, S607831



EPA Reviewer: Paul Long, Date 8/14/02

STUDY TYPE: Crop Field Trials - Pear; OPPTS 860.1500

TEST MATERIAL: Bifenthrin; PC Code 128825; CAS No. 82657-04-3

FORMULATION AND TYPE: Brigade® WSB Insecticide/Miticide (10% wettable-powder (WP) formulation in water soluble bag; EPA Reg. No. 279-3108)

SYNONYMS: FMC 54800; Capture®; Brigade®; Talstar®

CITATION: 45377302 Kim, I. (1993) Magnitude of the Residue of Bifenthrin in/on Pears Treated with Brigade® 10 WSB. FMC Corporation No.: 182PRS92R1; Report No. P-2792. Unpublished study prepared by FMC Corporation. 95 p.

45377303 Ridler, J.E. (1998) Magnitude of the Residue of Bifenthrin in/on Pears Following Treatment with Brigade® WSB Insecticide-Miticide. FMC Corporation No.: 182PRS97R1; Report No. P-3326. Unpublished study prepared by FMC Corporation. 72 p.

SPONSOR: FMC Corporation

EXECUTIVE SUMMARY:

FMC has submitted two studies depicting the magnitude of bifenthrin residues in/on pears. One study, reportedly submitted to support use of bifenthrin on pears in the northwest U.S., reflected application of a WP formulation (Brigade® WSB Insecticide/Miticide; 10% WP; EPA Reg. No. 279-3108) at 0.4x the proposed maximum seasonal rate. The second study reflected application of the 10% WP formulation using two different spray volumes, ~400 GPA, as specified on the proposed label, and ~50 GPA at 1x the proposed maximum seasonal rate. Previously submitted crop field trial data for pears have been determined to be adequate to support the proposed tolerance for residues of bifenthrin *per se* in/on pears at 0.5 ppm (PP#6F3454; CB Nos. 6715 and 7036-7044, 10-JAN-1991, N. Dodd).

The results from the crop field trial studies in pears have shown that residues of bifenthrin ranged 0.10-0.38 ppm in/on pears harvested 14 days following the last of three foliar applications of the 10% WP formulation of bifenthrin at 0.1, 0.2, and 0.2 lb ai/A in a spray volume of ~400 GPA for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate for pears). In side-by-side trials in which pears were treated at the same rate but with a spray volume of ~50 GPA, residues of bifenthrin ranged 0.12-0.43 ppm. The petitioner should submit a revised Section F for "pear" at 0.50 ppm.

The submitted pear field trial data are classified as acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500) in conjunction with previously submitted pear field trial data. However, the field trial data are not sufficient to support the petitioner's

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request to add lower spray volumes to the proposed label for pears.

The proposed 10% WP label specifies that ground applications be made in a minimum of 400 GPA. The petitioner concluded that because the maximum residues observed in/on pears treated using a reduced 50 GPA spray volume (0.43 ppm) were only slightly higher than in/on pears treated using a 400 GPA spray volume (0.38 ppm), the lower spray volume could be added to the proposed label. HED concludes that the submitted data are insufficient to allow HED to conclude that use of a concentrate spray volume will not result in increased residues in/on pears. In each of the three side-by-side trials conducted, residues in/on pears were higher with the 50 GPA spray volume than with the 400 GPA spray volume.

The OPPTS 860.1500 guidelines specify that a request to add another type of spray to a label requires a reduced number of field trials. To support the addition of concentrate spray volumes to the proposed label for pears, a minimum of 6 field trials is required; only three field trials with the concentrate spray volume have been conducted. Therefore, if the petitioner wishes to add concentrate spray volumes to the label for the 10% WP formulation, three additional crop field trials with pears utilizing a concentrate spray volume would be required. Alternatively, the petitioner may simply retain the minimum 400 GPA spray volume on the proposed label and no additional data will be required for pears.

The petitioner has now proposed the use of the 2 lb/gal emulsifiable concentrate (EC) formulation on pears. No crop field trial data reflecting application of the 2 lb/gal EC formulation to pears have been submitted previously. Because the proposed uses of bifenthrin are foliar applications, field trial data cannot be translated among the WP and EC formulation classes. Therefore, if the petitioner wishes to register the EC formulation for use on pears, crop field trial data reflecting application of the EC formulation at the maximum proposed application rates should be submitted. The petitioner should consult OPPTS 860.1500 for guidance on the number of field trials to conduct to support registration of a second formulation.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. The weather and soil data were not recorded in compliance with GLPs in the 1992 field trials.

I. MATERIALS AND METHODS

Samples of pears were analyzed for residues of bifenthrin using a gas chromatography (GC)/electron-capture detector (ECD) method (P-2792) which is a modification of the GC/ECD method originally submitted under this petition as an enforcement method (P-1073). Analysis was conducted at FMC Corporation (Princeton, NJ).

Briefly, samples from the 1992 field trials were extracted (2x) with acetone, a 5% sodium chloride solution was added, and the mixture was partitioned (2x) with hexane. The hexane phases were combined and concentrated. The combined hexane phase was applied to a Florisil solid phase extraction (SPE) cartridge for cleanup. Residues were eluted with 2.5% ethyl acetate in hexane, concentrated under nitrogen, and redissolved in hexane for analysis. Residue levels of bifenthrin were determined by GC analysis utilizing ECD; external standards were used for quantitation. The reported limit of detection (LOD) and validated limit of quantitation (LOQ) for residues of bifenthrin was 0.01 and 0.05 ppm, respectively, in/on pears.

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Samples from the 1997 field trials were extracted and analyzed as described above except that water was used instead of the 5% sodium chloride solution and a silica SPE cartridge was used instead of a Florisil cartridge. The petitioner stated that residues of bifenthrin in/on treated pears were qualitatively confirmed by GC/mass spectrometer (MS); however, actual results and representative chromatograms of the GC/MS analyses were not provided.

Concurrent method recovery data (presented below under I.4.) were submitted. Sample chromatograms of control and treated samples were provided; no interference was observed in the regions of bifenthrin in representative chromatograms for control samples. Based on the submitted concurrent recovery data, this method adequately recovers residues of bifenthrin from pears.

1. Test Compound

Chemical name:

IUPAC: 2-methylbiphenyl-3-ylmethyl (Z)-(1*RS*,3*RS*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

CAS name: (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate

CAS #: 82657-04-3 (cis)

Common name (ANSI, BSI or ISO): Bifenthrin

Developmental (Company) name: None specified

2. Trial Numbers and Locations

Crop/Pears	U.S. Growing Regions				Total Trials
	1	5	10	11	
Previously Submitted (1992; MR ID 41492606)	1	1	1	4	7
Submitted (1997; MRID 45377303)	--	--	1	2	3
Requested ¹	1	--	3	4	8

¹ As per OPPTS 860.1500, Table 5.

Comments: Geographic representation for bifenthrin on pears was considered adequate with previously submitted field trial data (PP#6F3454; CB Nos. 6715, 7036-7044, 10-JAN-1991, N. Dodd). The 1997 data (MRID 45377303) reviewed herein represent the maximum proposed use pattern for pears and were submitted to determine residues resulting in pear samples from side-by-side trials conducted using a reduced spray volume (50 GPA) versus the current proposed minimum spray volume (400 GPA). The 1992 data (MRID 45377302) reviewed herein *do not* represent the maximum proposed use pattern for pears and were reportedly submitted to support use of bifenthrin on pears in the northwest U.S.

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 EPA Barcodes: D274839, D280288

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3. Proposed Label Use Pattern

10% WP (EPA Reg. No. 279-3108)

2 lb/gal EC (EPA Reg. No. 3069)

Crop	Application					Comments/Restrictions
	Method/ Timing	Rate, lb ai/A	Maximum Number	Total Seasonal Rate, lb ai/A	PHI ^a , days	
Pears	Foliar	0.04-0.2	Not specified (NS)	0.5 (0.45 after petal fall)	14	Applications are to be made with a minimum 30-day retreatment interval. Applications may be made using ground equipment as a full cover dilute spray in a minimum of 400 GPA. Aerial applications may be made in a minimum of 10 GPA. The grazing of livestock or feeding of treated cover crops is prohibited.

^a PHI = pre-harvest interval

4. Analytical Method Validation (Concurrent)

Crop matrix (MRID)	Spiking Level, ppm	Recoveries obtained, %	Range, %	Mean ± SD, %
Pears (45377302)	0.05, 0.25	75, 77, 79, 81, 81, 101, 105, 106, 108, 113	75-113	93 ± 15
Pears (45377303)	0.05, 0.5	82, 85, 92, 95, 112, 120	82-120	98 ± 15

Comments: Based on the concurrent method recoveries, the GC/ECD method is adequate for data collection for residues of bifenthrin in/on pears.

5. Storage Stability Conditions

Commodity (MRID)	Storage Temperature, °C	Duration, days
Pears (1992; 45377302)	-18 (laboratory)	134-179
Pears (1997; 45377303)	-18 (laboratory)	276-314

Comments:

Whole pears from the 1997 field trials were frozen within 2 hours of harvest and shipped frozen within 20 days of harvest to FMC Corporation (Richmond, CA). Samples were stored frozen at the Richmond, CA facility and shipped frozen to FMC Corporation (Princeton, NJ) for residue analysis. Samples were analyzed within 3 days of extraction. The maximum frozen storage interval from collection to analysis was 314 days (~10 months) for pear samples.

Whole pears from the 1992 field trials were frozen within 2.5 hours of harvest and shipped frozen within 77 days of harvest to FMC Corporation (Princeton, NJ) for residue analysis. Samples were analyzed within 3 days of extraction. The maximum frozen storage interval from collection to analysis was 179

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days (~6 months) for pear samples.

Previous storage stability data have been submitted which indicate that residues of bifenthrin are stable for up to 49 months in/on frozen apples (Residue Chemistry Chapter of the Bifenthrin Tolerance Reassessment Eligibility Decision (TRED), DP Barcode D283808, S. Levy, currently under review). These data are adequate to support the storage conditions and intervals of the pear field trial samples.

6. Application and RAC Information

Three field trials were conducted in CA (EPA Region 10), OR (EPA Region 11), and WA (EPA Region 11) on pears during the 1997 growing season. Mature pear fruit were harvested 14 days following three broadcast foliar applications of the 10% WP formulation. The first application was made at 0.1 lb ai/A when the fruit were immature fruit; the second and third applications were made at 0.2 lb ai/A/application, with a 15- to 18-day retreatment interval for the second application and a 30- to 31-day retreatment interval for the third application. Two separate plots were treated at each trial site. Applications at one plot were made using ground equipment (airblast sprayers) in ~50 gal/A (GPA) and applications at the second plot were made using ground equipment in ~400 GPA; otherwise the treatment rates and timing were the same for the two treated plots. A third plot at each trial site was not treated to provide control samples. The treatment scheme of the field trials reflects the maximum proposed use rate and timing; applications were made at the concentrate spray volume (~50 GPA) for comparison with the current label restriction of a minimum of 400 GPA finished spray volume. Mature pears were harvested by hand from the top, middle, and bottom of the trees. A single untreated and duplicate treated samples (each treated plot), each consisting of ~24 fruits and weighing ~7-17 lbs, were collected from each trial site.

Five field trials were conducted in CA (EPA Region 10; 1 trial), OR (EPA Region 12; 2 trials), and WA (1 trial each in EPA Regions 11 and 12) on pears during the 1992 growing season; these data do not represent the maximum proposed seasonal rate for pears and, therefore, are presented for informational purposes only. Mature pear fruit were harvested 30 and 45 days following two broadcast foliar applications of the 10% WP formulation at 0.1 lb ai/A/application, with 30- to 53-day retreatment intervals, for a total rate of 0.2 lb ai/A (0.4x). Applications were made using ground equipment (airblast sprayers) in ~25 gal/A (GPA) in water. A separate plot at each trial site was not treated for controls. Mature pears were harvested by hand or using a pole-picker. A single untreated and duplicate treated samples, each consisting of 30-32 (untreated) or 16-30 (treated) lbs or fruits, were collected from each trial site at both PHI intervals.

7. Site Specific Information

The soils from the field trials were classified as very fine sandy loam, fine sandy loam, sandy loam, loam, and/or silt loam; pH and % organic matter of the soil were provided for the 1992 field trials, but no additional soil characteristics were provided for the 1997 field trials. Weather conditions during the field trials were considered normal for the area for the 1997 trials. Temperature and precipitation data were reported for the 1992 trials, but 10-year averages were not reported; therefore, the weather conditions during the trials could not be compared with normal conditions. Fertilizers and/or maintenance chemicals used at the trial sites are not expected to affect the residue data.

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II. RESULTS

TABLE 1. Residue Data Summary from Crop Field Trials

Location (city, state)/ Year	Crop/ Variety	Commodity/ Portion analyzed	Formulation (spray volume) ^a	Application				PHI, days	Bifenthrin Residues, ppm ^b	
				Rate, lb ai/A	# of Appl.	Interval Between Appls., days	Total Rate, lb ai/A			Percent of Max Rate
Live Oak, CA/ 1992	Pear/Bartlett	Fruit	10% WP (25 GPA)	0.1	2	31	0.2	40	30	0.05, 0.21
									45	0.10, 0.12
Hillsboro, OR/ 1992	Pear/Bartlett	Fruit	10% WP (25 GPA)	0.1	2	39	0.2	40	30	(0.04), 0.18
									45	0.08, 0.12
Harrisburg, OR/ 1992	Pear/Bosc	Fruit	10% WP (25 GPA)	0.1	2	37	0.2	40	30	0.06, 0.07
									45	0.07, 0.11
Vancouver, WA/ 1992	Pear/Bartlett	Fruit	10% WP (25 GPA)	0.1	2	39	0.2	40	30	(0.03), 0.07
									45	0.09, 0.14
Walla Walla, WA/ 1992	Pear/Red Bartlett	Fruit	10% WP (25 GPA)	0.1	2	40	0.2	40	30	(0.02), (0.03)
									45	<0.01, (0.04)
Clarksburg, CA/ 1997	Pear/Bartlett	Fruit	10% WP (399-435 GPA)	0.1, 0.2, 0.2	3	18, 31	0.5	100	14	0.10, 0.14
			10% WP (53-54 GPA)							
Hood River, OR/ 1997	Pear/ Bartlett	Fruit	10% WP (401-413 GPA)	0.1, 0.2, 0.2	3	15, 31	0.5	100	14	0.14, 0.21
			10% WP (50-51 GPA)							

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Location (city, state)/ Year	Crop/ Variety	Commodity/ Portion analyzed	Formulation (spray volume) ^a	Application				PHI, days	Bifenthrin Residues, ppm ^b
				Rate, lb ai/A	# of Appl.	Interval Between Appls., days	Total Rate, lb ai/A		
Zillah, WA/ 1997	Pear/Bartlett	Fruit	10% WP (~400 GPA)	0.1, 0.2, 0.2	3	16, 30	0.5	100	0.27, 0.38
			10% WP (~50 GPA)						

^a Application spray volumes in gal/A water (GPA) are reported in parentheses; the proposed label specifies that ground applications be made in a minimum of 400 GPA.

^b Residues reported in parentheses are estimated values between the LOD (0.01 ppm) and LOQ (0.05 ppm); residues representative of the maximum proposed use are **bolded**.

Apparent residues of bifenthrin were nondetectable (<0.01 ppm) in/on 13 samples of untreated pears (3 from the 1997 field trials and 10 from the 1992 field trials).

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Comments:

The submitted 1997 pear field trials indicate that residues of bifenthrin ranged 0.10-0.38 ppm in/on pears harvested 14 days following the last of three foliar applications of the 10% WP formulation of bifenthrin at 0.1, 0.2, and 0.2 lb ai/A in a spray volume of ~400 GPA for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate for pears). The FTMaR of bifenthrin in/on samples treated using ~400 GPA was 0.21 ppm for pears. Residues of bifenthrin ranged 0.12-0.43 ppm in/on pears harvested 14 days following the last of three foliar applications of the 10% WP formulation of bifenthrin at 0.1, 0.2, and 0.2 lb ai/A in a spray volume of ~50 GPA for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate for pears, but at a lower spray volume than specified on the proposed label). The FTMaR of bifenthrin in/on samples treated using ~50 GPA was 0.28 ppm for pears.

The 1992 pear field trial data do not represent the maximum proposed seasonal rate for pears and are presented for informational purposes only. Residues of bifenthrin ranged 0.02 (below the LOQ of 0.05 ppm)-0.21 ppm and <0.01 (<LOD)-0.14 ppm in/on pears harvested 30 and 45 days, respectively, following the last of two foliar applications of the 10% WP formulation of bifenthrin at 0.1 lb ai/A/application in a spray volume of ~25 GPA for a total rate of 0.2 lb ai/A (0.4x the maximum proposed seasonal rate for pears).

III. CONCLUSIONS

The results from the crop field trial studies in pears have shown that residues of bifenthrin ranged 0.10-0.38 ppm in/on pears harvested 14 days following the last of three foliar applications of the 10% WP formulation of bifenthrin at 0.1, 0.2, and 0.2 lb ai/A in a spray volume of ~400 GPA for a total rate of 0.5 lb ai/A (1x the maximum proposed seasonal rate for pears). In side-by-side trials in which pears were treated at the same rate but with a spray volume of ~50 GPA, residues of bifenthrin ranged 0.12-0.43 ppm.

The submitted pear field trial data are classified as acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500) in conjunction with previously submitted pear field trial data. However, the field trial data are not sufficient to support the petitioner's request to add lower spray volumes to the proposed label for pears. The petitioner should submit a revised Section F for "pear" at 0.50 ppm.

The proposed 10% WP label specifies that ground applications be made in a minimum of 400 GPA. The petitioner concluded that because the maximum residues observed in/on pears treated using a reduced 50 GPA spray volume (0.43 ppm) were only slightly higher than in/on pears treated using a 400 GPA spray volume (0.38 ppm), the lower spray volume could be added to the proposed label. HED concludes that the submitted data are insufficient to allow HED to conclude that use of a concentrate spray volume will not result in increased residues in/on pears. In each of the three side-by-side trials conducted, residues in/on pears were higher with the 50 GPA spray volume than with the 400 GPA spray volume.

The OPPTS 860.1500 guidelines specify that a request to add another type of spray to a label requires a reduced number of field trials. To support the addition of concentrate spray volumes to the proposed label for pears, a minimum of 6 field trials is required; only three field trials with the concentrate spray volume have been conducted. Therefore, if the petitioner wishes to add concentrate spray volumes to the

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label for the 10% WP formulation, three additional crop field trials with pears utilizing a concentrate spray volume would be required. Alternatively, the petitioner may simply retain the minimum 400 GPA spray volume on the proposed label and no additional data will be required for pears.

The petitioner has now proposed the use of the 2 lb/gal EC formulation on pears. No crop field trial data reflecting application of the 2 lb/gal EC formulation to pears have been submitted previously. Because the proposed uses of bifenthrin are foliar applications, field trial data cannot be translated among the WP and EC formulation classes. Therefore, if the petitioner wishes to register the EC formulation for use on pears, crop field trial data reflecting application of the EC formulation at the maximum proposed application rates should be submitted. The petitioner should consult OPPTS 860.1500 for guidance on the number of field trials to conduct to support registration of a second formulation.

IV. STUDY DEFICIENCIES

Three additional crop field trials are required if the petitioner wishes to add concentrate spray volumes to the proposed use directions for the 10% WP formulation on pears. In addition, if the petitioner wishes to register the EC formulation for use on pears, crop field trial reflecting application of the EC formulation to pears should be submitted.



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