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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: August 29, 2017

SUBJECT: **Bifenthrin:** Human Health Draft Risk Assessment for Registration Review, and Section 3 Risk Assessment for Proposed Uses on Avocado, *Brassica* Leafy Greens Subgroup 4-16B, Low Growing Berry Subgroup 13-07 G, Peach subgroup 12-12B, Pepper/Eggplant Subgroup 8-10B, Pome Fruit 11-10 (except mayhaw), Pomegranate, Small Vine Climbing Subgroup 13-07F, Tomato Subgroup 8-10A; and Crop Group Conversions for Citrus Group 10-10, Caneberry Subgroup 13-07A, and Tree Nut Group 14-12.

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As part of Registration Review, the Pesticide Re-Evaluation Division (PRD) of the Office of Pesticide Programs (OPP) has requested that HED evaluate the hazard and exposure data and conduct dietary (food and drinking water), residential, aggregate, and occupational exposure assessments to estimate the risk to human health that will result from the currently registered uses of pesticides. This memorandum serves as HED's draft human health risk assessment of the dietary, residential, aggregate, and occupational exposures and risks from the registered uses of bifenthrin.

Bifenthrin has also been proposed for use on the following agricultural commodities by the Inter-Regional Project No. 4 (IR-4): avocado, *Brassica* leafy greens subgroup 4-16B, low growing berry subgroup 13-07G, peach subgroup 12-12B, pepper/eggplant subgroup 8-10B, pome fruit group 11-10 (except mayhaw), pomegranate, small vine climbing subgroup 13-07F, and tomato subgroup 8-10A. The following crop group conversions have also been proposed by IR-4: citrus group 10-10, caneberry subgroup 13-07A, and tree nut group 14-12. Therefore, this memorandum also serves as HED's Section 3 human health risk assessment of the dietary, residential, aggregate, and occupational exposures from the proposed uses of bifenthrin.

The most recent human health risk assessment was performed in 2016 (K. Rickard, D435062, 09/08/2016). The following risk assessment updates have been made:

- A route-specific inhalation toxicity study was selected for inhalation risk assessment;
- The dietary exposure assessment has been updated to incorporate the proposed new uses of bifenthrin;
- The registered residential uses of bifenthrin have been reevaluated using the updated inhalation risk assessment point of departure (POD), the revised Residential Standard Operating Procedures (SOPs), and chemical-specific dislodgeable foliar residue (DFR) and turf transferrable residue (TTR) studies;
- An aggregate exposure assessment was completed, including updated dietary and residential exposure estimates;
- A non-occupational spray-drift exposure/risk assessment was completed; and
- An occupational exposure assessment for the registered and proposed uses was completed reflecting recent updates to the bifenthrin points of departure, and policy changes for body weight, unit exposure, and area/amount treated assumptions.

A summary of the findings and an assessment of human risk resulting from the registered and proposed uses of bifenthrin are provided in this document.

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1.0 Executive Summary

Bifenthrin (2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate) is an insecticide, miticide, and termiticide in the class of pyrethroids.

This human health risk assessment includes an evaluation of both the existing and proposed uses of bifenthrin. In order to evaluate the proposed and existing uses of bifenthrin, highly-refined dietary exposure and risk assessments were conducted for three scenarios: (1) all existing uses of bifenthrin; (2) all existing and proposed uses of bifenthrin; and (3) because the acute dietary exposures for the proposed and existing uses resulted in risk estimates of concern, and a critical exposure commodity (CEC) analysis indicated that the commodities within crop group 4-16B were the major contributors to the acute dietary exposure estimates, a third dietary exposure analysis was conducted to help inform risk management decisions under registration and Registration Review. The third analysis incorporated all existing and proposed uses of bifenthrin with an alternative use pattern for *Brassica* leafy greens subgroup 4-16B. The third analysis was conducted because the acute dietary exposures for the proposed and existing uses resulted in risk estimates of concern, and to help inform risk management decisions under registration and Registration Review.

Use Profile – Existing Uses

Bifenthrin is registered for use on various agricultural field and orchard/vineyard crops, ornamentals (indoor and outdoor nurseries and greenhouses), Christmas tree farms and pine seed orchards, turf (sod farms, lawns, golf courses), and outdoor (commercial and residential) perimeter treatments. It is also registered for use as a termiticide; as a dog shampoo; as an indoor/outdoor surface treatment for residential, institutional, public, commercial, industrial, and livestock/poultry premises; and as a seed treatment for various food/feed crops. Bifenthrin is currently formulated as liquid, granule, wettable powder in water soluble bags (WSB), dust, and ready-to-use (RTU) end-use-products (EUPs). Most of the registered products are applied either via aerial, chemigation, airblast, or groundboom equipment; granular spreaders; or with handheld equipment. Seed treatments are expected to occur in commercial treatment facilities or on-farm facilities. Labels vary with respect to requirements for work attire and personal protective equipment (PPE). Those EUPs requiring PPE beyond baseline attire and chemical resistant gloves are co-formulations with other active ingredients. The representative agricultural labels contain restricted entry intervals (REIs) of 12 hours.

Use Profile – Proposed Uses

IR-4 has submitted a petition for establishing permanent Section 3 tolerances for bifenthrin on: avocado, *Brassica* leafy subgroup 4-16B, low growing berry subgroup 13-07G, peach subgroup 12-12B, pepper/eggplant subgroup 8-10B, pome fruit group 11-10 (except mayhaw), pomegranate, small vine climbing subgroup 13-07F, and tomato subgroup 8-10A. IR-4 has also proposed crop group conversions for citrus group 10-10, caneberry subgroup 13-07A, and tree nut group 14-12. Some or all of these uses are requested to be added to seven EUP labels (EPA Reg. Nos. 279-3108, 279-3313, 279-3315, 279-3329, 66222-99, 66222-261, and 66222-236). Some of the proposed commodities and some of the commodities within the proposed crop groups or crop group expansions have existing Section 18 emergency exemption tolerances for

bifenthrin (apple, avocado, nectarine, peach, and pomegranate). The new uses are proposed on liquid formulation EUPs; all of which are restricted use pesticides (RUPs) due to toxicity to fish and aquatic organisms. Applications can be made using ground, airblast, aerial, and chemigation application equipment for most crops and application types; soil-directed application in citrus orchards are restricted to ground and handheld applications only. All proposed labels require occupational handlers to wear baseline attire (long sleeved shirts, long pants, shoes, socks) and chemical resistant gloves; mixer/loaders or others exposed to the concentrate are also required to wear protective eyewear. The REI for the proposed uses of bifenthrin is 12 hours.

Exposure Profile

Acute and chronic dietary exposures are expected from the proposed and existing uses of bifenthrin. Non-dietary exposure to bifenthrin may occur from occupational and residential exposure sources. Occupational non-dietary (dermal and inhalation) handler and post-application exposure is expected to be both short- (1 to 30 days) and intermediate-term (1 to 6 months) based on information provided on the proposed labels. Residential non-dietary exposures and exposures from spray drift are expected to be short-term only. However, bifenthrin does not increase in toxicity with repeated dosing. As such, only single day, non-dietary exposures were assessed.

Hazard Considerations

The toxicology database for bifenthrin is considered complete with respect to guideline toxicity studies. Pyrethroids have historically been classified into two groups, Type I and Type II, based upon chemical structure and toxicological effects. Bifenthrin is a Type I pyrethroid. Toxicological effects characteristic of Type I pyrethroids, such as muscle tremors, were seen in most of the bifenthrin experimental toxicology studies.

The endpoint of decreased motor activity observed in the acute oral Wolansky study (an acute non-guideline study conducted for several pyrethroids; Wolansky, et. al., 2006) was used for the dietary (acute) and incidental oral scenarios because it was considered to be the most robust data set for assessing bifenthrin exposure and risk. Due to the lack of increased hazard from repeated/chronic exposure to bifenthrin, the risk estimates derived from use of the acute study are protective of risk from repeated exposures. For acute dietary, short-term oral, short-term incidental oral, and episodic granular ingestion, the point of departure (POD) is based on reductions in motor activity seen in the acute oral rat study at a benchmark dose one control standard deviation from the control value (BMD_{1SD}) of 4.1 mg/kg [lower 95% confidence limit on the benchmark dose ($BMDL_{1SD}$) value of 3.1 mg/kg]. For dermal risk assessment, the POD is based on exaggerated hind limb flexion seen in the 21-day dermal rat study at a benchmark dose associated with a 10% response (BMD_{10}) value of 187 mg/kg/day [benchmark dose (BMD) lower confidence bound ($BMDL_{10}$) = 96.3 mg/kg/day]. For inhalation risk assessment, the POD is based on tremors and increased respiration rates seen in the 28-day inhalation toxicity study at the lowest observed adverse effect level (LOAEL) of 0.0196 mg/L/day [no observed adverse effect level (NOAEL) = 0.0059 mg/L/day]. Human Equivalent Concentrations (HECs)/Human Equivalent Doses were calculated for residential and occupational scenarios. Since the toxicological endpoints for dermal, incidental oral, and inhalation are based on similar effects (neurotoxicity), the risks from these exposures routes can be combined when appropriate.

In conjunction with the completion of the pyrethroid cumulative risk assessment (K. Whitby, D394576, 10/4/2011, EPA-HQ-OPP-2011-0746-0003), HED determined that the Food Quality Protection Act Safety Factor (FQPA SF) can be reduced to 1X for adults and children ≥6 years old. The Agency is retaining a 3X FQPA SF to protect children <6 years of age based on the pyrethroid pharmacokinetic (PK) difference between adults and children <6 years old that leads to the increased quantitative juvenile susceptibility observed in high dose studies in the literature. For assessing residential and occupational dermal risks to adults, and residential dermal to children ≥ 6 years old, the level of concern (LOC) is 100 [10X interspecies uncertainty factor (UF), 10X intraspecies UF, and a 1X FQPA SF (residential exposures only)]. For assessing dermal, incidental oral, and acute (episodic) ingestion risks to children < 6 years old, the LOC is 300 (10X interspecies UF, a 10X intraspecies UF, and a 3X FQPA SF).

For assessing residential and occupational inhalation risks for adults, and residential inhalation risks for children ≥ 6 years old, the LOC is 30 [(3X interspecies UF, a 10X intraspecies UF, and a 1X FQPA SF (residential exposures only)]. The standard interspecies extrapolation UF is reduced from 10X to 3X due to the calculation of HECs accounting for pharmacokinetic (not pharmacodynamic) interspecies differences. For assessing inhalation risks for children < 6 years old, the LOC is 100 (10X interspecies, 3X intraspecies, and 3X FQPA SF) was used.

HED has classified bifenthrin as a Group C carcinogen (possible human carcinogen) primarily on the basis of a mouse study in which the high-dose males showed an increased incidence of urinary bladder tumors; a Q_1* has not been derived, however, the acute endpoint/POD is considered protective for any potential carcinogenic effects.

Residue Chemistry

The residue chemistry database is complete for bifenthrin and adequate field trial data have been provided to support the proposed uses. The nature of the residue in plants is adequately understood for the purposes of this petition based on previously reviewed plant metabolism studies. Field trials are of adequate number and geographic representation. Crop field trial data analyses employed validated gas chromatography with an electron capture detector (GC/ECD) analytical methods, and are supported by adequate storage stability data. An adequate GC/ECD analytical enforcement method is available to enforce bifenthrin tolerances. Tolerance recommendations were based on use of the Organization for Economic Cooperation and Development (OECD) Maximum Residue Limit (MRL) calculation procedures, international harmonization considerations, and data translation where appropriate.

Dietary Exposure and Risk Assessment

Highly refined acute dietary exposure and risk assessments were conducted for bifenthrin using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID; Ver. 3.18). Refined average (chronic) exposure assessments were conducted for the purposes of the bifenthrin aggregate assessment. For drinking water, the Environmental Fate and Effects Division (EFED) modeled the estimated drinking water concentrations (EDWCs) for bifenthrin based on the maximum use rate of application. Modeled EDWCs did not exceed the very low solubility limit of bifenthrin (0.000014 ppm); therefore, the solubility limit was incorporated into the dietary assessment to assess exposures to drinking water. The dietary exposure assessments were refined using United States Department of Agriculture (USDA)

Pesticide Data Program (PDP) monitoring data, field trial data, percent crop treated (PCT) data, and empirical processing factors.

In order to evaluate the proposed and existing uses of bifenthrin, highly-refined dietary exposure and risk assessments were conducted for three scenarios: (1) all existing uses of bifenthrin; (2) all existing and proposed uses of bifenthrin; and (3) all existing and proposed uses of bifenthrin with an alternative use pattern for *Brassica* leafy greens subgroup 4-16B.

Existing Uses
There were no acute dietary (food and drinking water) exposure risk estimates of concern for the U.S. population and all population subgroups for the existing uses of bifenthrin. At the 99.9th percentile of exposure, the acute dietary risk estimate is 6.2% of the acute population-adjusted dose (aPAD) for the general U.S. population and 51% of the aPAD for all infants (< 1 year old), the most highly exposed population subgroup. The average (chronic food and drinking water) exposure assessment was conducted solely for the purposes of obtaining dietary exposure estimates for use only in estimating background dietary exposures for the aggregate assessment. The population subgroup with the highest average dietary (food and drinking water) exposure estimate is children 1-2 years old (0.000218 mg/kg/day).

Existing and Proposed Uses
Most of the requested tolerances by IR-4 have already been incorporated into the dietary exposure assessment as registered Section 18 uses, or are requested crop group conversions which would not impact the dietary exposure estimates. The only new use pattern proposed is reducing the existing pre-harvest interval (PHI) for *Brassica* leafy subgroup 4-16B crops from 7-days to 1-day. Because this is a new use pattern and monitoring data are not applicable, field trial data were used in the dietary exposure assessment to represent crops in subgroup 4-16B.

For the existing and proposed uses of bifenthrin, the acute dietary (food and drinking water) risk estimates are <u>of concern</u> at the 99.9th percentile of exposure for multiple population subgroups. At the 99.9th percentile of exposure, the acute dietary risk estimate is 48% of the aPAD for the general U.S. population and 330% of the aPAD for children 1 to < 2 years old, the most highly exposed population subgroup. A critical exposure commodity analysis (CEC) found that commodities within group 4-16B were the major contributors to the acute dietary exposure estimates. The average (chronic food and drinking water) exposure assessment was conducted solely for the purposes of obtaining background dietary exposure assessments for use in the aggregate assessment. The population subgroup with the highest average dietary (food and drinking water) exposure estimate is children 1-2 years old (0.000327 mg/kg/day).

Existing and Proposed Uses – Alternative Use Pattern
Because the acute dietary exposures for the proposed and existing uses resulted in risk estimates of concern, and a critical exposure commodity (CEC) analysis indicated that the commodities within crop group 4-16B were the major contributors to the acute dietary exposure estimates, a third dietary exposure analysis was conducted to help inform risk management decisions. The third analysis incorporated the existing and proposed uses of bifenthrin, except available monitoring data on mustard greens (the representative crop for subgroups 5B and 4-16B) were

extrapolated to crops contained in subgroup 4-16B. The monitoring data are representative of a PHI of 7-days (rather than the proposed PHI of 1-day).

There were no acute dietary (food and drinking water) exposure and risk estimates of concern for the existing and proposed uses of bifenthrin assuming the existing 7-day PHI for *Brassica* leafy greens subgroup 4-16B. At the 99.9th percentile of exposure, the acute dietary risk estimate is estimated to be 6.2% of the aPAD for the general U.S. population, and 51% of the aPAD and for all infants (< 1 year old), the most highly exposed population subgroup. The average (chronic food and drinking water) exposure assessment was conducted solely for the purposes of obtaining background dietary exposure estimates for use in the aggregate assessment. The population subgroup with the highest average dietary (food and drinking water) exposure estimate is children 1-2 years old (0.000218 mg/kg/day).

Residential Exposure and Risk Assessment – Existing Uses

There are registered bifenthrin product labels with residential use sites (e.g., lawns, indoor environments, garden and trees, and pets) that do not require specific clothing (e.g., long sleeve shirt/long pants) and/or PPE, and these labels have been considered in the residential handler assessment for bifenthrin. A screening-level approach was used for assessment of residential exposures by evaluation of the maximum application rate for all possible residential handler exposure scenarios of bifenthrin. There are no dermal or inhalation risk estimates of concern for residential handlers (ARIs >1) for the registered uses of bifenthrin. Bifenthrin-specific turf transferrable residue (TTR) and dislodgeable foliar residue (DFR) data are available and were used in the residential-post-application assessment. Post-application dermal, and/or incidental oral margins of exposure (MOEs) were not of concern following indoor treatments and/or from contact with treated dogs. However, some post-application risk estimates were of concern following treatments to lawns/turf using bifenthrin-specific TTR data. There are no residential exposures expected from the proposed uses of bifenthrin.

Aggregate Exposure and Risk Assessment

The acute aggregate assessment is equivalent to the acute dietary exposure and risk estimates, and risks of concern were identified when evaluating the proposed and existing uses of bifenthrin (risk estimates greater than 100% of the aPAD). Additionally, some short-term residential scenarios (turf) result in risk estimates of concern (MOEs < LOC) for both the dermal and incidental oral routes of exposure for adults and children. These residential exposure scenarios have not been considered for the purpose of performing an aggregate assessment since additional exposure from food and water would only increase the risk estimates. Because acute dietary risk estimates of concern were identified for the proposed uses of bifenthrin, three dietary exposure assessment scenarios were conducted to generate average (chronic) dietary exposure and risk assessments to inform risk management decisions for the proposed and existing uses of bifenthrin. Average food and drinking water estimates were combined with potential residential exposures to generate an aggregate exposure and risk assessment.

All Existing Uses of Bifenthrin

There were no short-term aggregate (food, drinking water, residential exposures) risk estimates of concern for adults (MOE = 210, LOC = 100), children 1 to <2 years old (MOE = 430, LOC =

300), children 6 to < 11 years old (MOE = 960, LOC = 100), or children 11 to < 16 years old (MOE = 1,700, LOC = 100).

All Existing and Proposed Uses of Bifenthrin
There were no short-term aggregate (food, drinking water, residential exposures) risk estimates of concern for adults (MOE = 210, LOC = 100), children 1 to <2 years (MOE = 420, LOC = 300), children 6 to < 11 years old (MOE = 940, LOC = 100), and children 11 to < 16 years old (MOE = 1,600, LOC = 100).

All Existing and Proposed Uses – Alternative Use Pattern
The were no short-term aggregate (food, drinking water, residential exposures) risk estimates of concern for adults (MOE = 210, LOC = 100), children 1 to <2 years (MOE of 430, LOC = 300), children 6 to < 11 years old (MOE = 960, LOC = 100), and children 11 to 16 years old (MOE = 1,700, LOC = 100).

Non-Occupational Spray Drift Exposure and Risk Assessment
A quantitative spray drift assessment was conducted for the proposed and existing uses of bifenthrin. Even though there are registered uses for direct treatment of residential turf, these uses resulted in some post-application risk estimates of concern for adults and children 1 to < 2 years old; therefore, they cannot be considered protective of potential spray drift exposure. The spray drift assessment incorporated the maximum proposed and registered application rate to a crop/target site expected to result in spray drift (0.4 lb ai/A)[1]. There were no dermal risk estimates of concern at the field edge for adults following applications to any registered crops at the maximum registered application rates and assuming screening-level droplet sizes and boom heights (MOEs ≥ 100). Further, there were no combined dermal and incidental oral risk estimates of concern at the field edge for children 1 to < 2 years old, except from aerial applications to tobacco (0.4 lb ai/A). At the field edge, combined dermal and incidental oral MOEs ranged from 280 to 4,900 (level of concern; LOC = 300). Aerial sprays to tobacco required distances of 10 feet from the field edge to result in combined risk estimates not of concern (MOE = 350).

The impact of changing nozzle types resulting in coarser sprays, which drift less, reduces risks from aerial and ground applications. Similarly, using coarser sprays and lowering the boom height for groundboom sprayers, or applying to denser crop canopies with airblast sprayers lowers risk concerns.

Occupational Handler Exposure and Risk Assessment - Existing Uses
HED summarized the existing bifenthrin use pattern by evaluating representative registered EUP labels and use sites. This summary of uses was then reviewed by the Biological Economic Analysis Division (BEAD). The majority of the occupational handler dermal, inhalation, and combined (dermal + inhalation) risk estimates are not of concern for the existing uses of bifenthrin (MOEs ≥ 100 for dermal, ≥ 30 for inhalation, and ARIs ≥ 1) with baseline attire. Based on the representative labels/uses evaluated, all scenarios of concern assuming baseline attire were not of concern with current label-specified PPE (chemical resistant or waterproof

[1] The spray drift assessment did not consider applications to tree trunks for trees grown for non-commercial purposes (0.6 lb ai/A) as a directed spray applied with a handgun sprayer. Spray drift is not expected with handheld equipment.

gloves), except mixing/loading/applying liquids with a mechanically pressurized handgun for soil at-plant applications to tobacco. At-plant tobacco applications required baseline attire, chemical resistant gloves, and a double layer of clothing to result in risk estimates not of concern (ARI ≥ 1), while the representative label evaluated requires handlers to wear only baseline attire (EPA Reg. No. 279-3332).

Occupational Handler Exposure and Risk Assessment – Proposed Uses

All of the occupational handler dermal, inhalation, and combined (dermal + inhalation) risk estimates for the proposed uses of bifenthrin are not of concern (MOEs ≥ 100 for dermal, ≥ 30 for inhalation, and ARIs ≥ 1) with baseline attire.

Occupational Post-Application Exposure and Risk Assessment – Existing and Proposed Uses

EPA has determined that there are potential short- and intermediate-term post-application exposures to individuals entering treated fields. All dermal post-application exposures were not of concern (MOE ≥ 100) on the day of application (Day 0) using bifenthrin-specific dislodgeable foliar residue (DFR) and turf transferrable residue (TTR) data and assuming maximum application rates and transfer coefficients (TCs) for each scenario. The occupational post-application MOEs representing the worst-case activity scenario for each crop range from 190 to 8,200.

Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for re-entry workers exposed to indirect residues of bifenthrin resulting from outdoor uses.

Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.[2]"

Human Studies

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their exposure. Appendix C provides additional information on the review of human research used to complete the risk assessment. There is no regulatory barrier to continued reliance on these studies, and all applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40CFR Part 26) have been satisfied (see Appendix C).

[2] https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice

2.0 Risk Assessment Conclusions and Recommendations

Acute dietary exposure and risk estimates are not of concern to HED for the existing and proposed uses of bifenthrin when assuming the existing 7-day PHI for *Brassica* leafy greens subgroup 4-16B. Some non-dietary exposure scenarios on treated turf resulted in post-application risk estimates of concern for adults and children. These exposure scenarios have not been considered for the purpose of performing an aggregate assessment since additional exposure from food and water would only increase the risk estimates. Additionally, acute dietary and aggregate risk estimates of concern were identified for the existing and proposed uses of bifenthrin assuming the requested 1-day PHI for *Brassica* leafy greens subgroup 4-16B. Therefore, the proposed tolerance on Brassica leafy greens subgroup 4-16B with the 1-day PHI is not recommended. Pending submission of revised Sections B (Section 2.2) and F (Section 2.1.3), there are no residue chemistry or dietary considerations that preclude establishment of the recommended tolerances.

There are some short-term residential risk estimates of concern for the existing uses of bifenthrin (post-application exposures to lawns/turf).

When aggregating residential risk estimates that were not of concern with average (chronic) food and drinking water exposures, there were no short-term aggregate risk estimates of concern for bifenthrin. Residential risk estimates that were of concern were not aggregated because the additional exposure from food and water would only increase the risk estimates.

At the field edge, there were no non-occupational spray drift dermal risk estimates of concern for adults and no combined dermal and incidental oral risk estimates of concern for children 1 to < 2 years old, except from aerial applications to tobacco (0.4 lb ai/A). Aerial sprays to tobacco required distances of 10 feet to result in risk estimates not of concern assuming screening-level droplet sizes and maximum application rates.

The majority of the occupational handler dermal, inhalation and combined (dermal + inhalation) risk estimates are not of concern for the existing uses of bifenthrin with baseline attire. Based on the representative labels evaluated, all scenarios of concern assuming baseline attire were not of concern with label-specified PPE (chemical resistant or waterproof gloves), except mixing/loading/applying liquids with a mechanically pressurized handgun for soil at-plant applications to tobacco. At-plant tobacco applications required baseline attire, chemical resistant gloves, and a double layer of clothing to result in risk estimates not of concern. All dermal post-application exposures were not of concern on the day of application.

2.1 Data Deficiencies

TTR and DFR data using liquid formulation applications are available for bifenthrin. Although no specific data are required at this time; additional TTR/DFR data using a granular formulation could be submitted to refine the residential and occupational post-application assessments.

2.1.1 Enforcement Analytical Method

Adequate tolerance enforcement methods are available based on Gas Chromatography with an Electron Capture Detector (GC/ECD) analyses for determining bifenthrin residues in both plant and livestock commodities. The method for plant commodities was developed by the registrant and works by performing sample extraction with acetone. The sample extracts are then partitioned with hexane and purified using a Florisil column followed by the determination of residues by GC/ECD analysis. For livestock commodities, FMC method P-1031 was similarly developed by the registrant using GC/ECD analyses for the enforcement of bifenthrin tolerances in milk and ruminant tissues. The reported limit of quantitation (LOQ) for these methods is 0.05 ppm and in some cases sample extracts may be analyzed by GC/MSD instead of GC/ECD for the purpose of quantitation.

2.1.2 Recommended Tolerances

Table 2.1.2 summarizes the bifenthrin tolerances recommended based on the proposed new uses and crop group conversions, as well as the revisions for harmonization with established international MRLs. In addition, the established tolerance for the *Brassica*, head and stem, subgroup 5A, except cabbage can also be converted to the newly formed crop grouping. Following the conversion plan for implementation, this crop grouping can be deleted from the federal register and replaced with the establishment of vegetable, head and stem *Brassica*, group 5-16, except cabbage at 0.90 ppm along with a separate tolerance for kohlrabi at 0.90 ppm since this crop is not carried into the new grouping. Further, the established tolerance for leaf petioles subgroup 4B can also be deleted from the federal register and converted to the new leaf petiole vegetable subgroup 22B. Because celtuce, Florence fennel, and Swiss chard are not carried into this new grouping, separate tolerances must also be established for these commodities at 3.0 ppm. A tolerance on *Brassica*, leafy greens subgroup 4-16B is not recommended at the proposed new pattern of use following a 1-day PHI. However, implementation of the conversion plan allows the *Brassica*, leafy greens subgroup 5B to be deleted from the federal register and replaced with the new subgroup 4-16B at a tolerance of 3.5 ppm following the established 7-day PHI. The established tolerances are listed in Appendix E.

Table 2.1.2. Tolerance Summary for Bifenthrin (40 CFR § 180.442).

Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments *Correct Commodity Definition*
Apple, wet pomace	--	1.3	1.5[1]	
Avocado	--	0.50	0.50	
Beet, garden, roots	0.45	--	0.50	*Tolerance is harmonized to the Canadian MRL*
Berry, low growing, subgroup 13-07G	--	3.0	3.0	
Brassica, head and stem, group 5-16, except cabbage	0.60	--	0.90	*Updated crop group conversion with tolerance harmonized to the Canadian MRL*
Brassica, leafy greens, subgroup 4-16B	--	15	3.5	*Updated crop group conversion*
Caneberry subgroup 13-07A	1.0	--	1.0	

Table 2.1.2. Tolerance Summary for Bifenthrin (40 CFR § 180.442).

Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments *Correct Commodity Definition*
Celtuce	3.0	--	3.0	*Updated crop group conversion*
Fennel, Florence	3.0	--	3.0	*Updated crop group conversion*
Swiss chard	3.0	--	3.0	*Updated crop group conversion*
Fruit, citrus, group 10-10	0.05	--	0.05	
Fruit, pome, group 11-10, except mayhaw[2]	--	0.70	0.90	*Tolerance is harmonized to the Canadian MRL set on pears*
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	--	0.20	0.20	
Kohlrabi	0.60	--	0.90	*Updated crop group conversion with tolerance harmonized to the Canadian MRL*
Leaf petiole vegetable subgroup 22B	3.0	--	3.0	*Updated crop group conversion*
Mayhaw	1.4	--	1.5	*Tolerance is harmonized to the Canadian MRL*
Nut, tree, group 14-12	0.05	--	0.05	
Peach subgroup 12-12B	--	0.70	0.70	
Pepper/eggplant subgroup 8-10B	--	0.50	0.50	
Pomegranate	--	0.50	0.50	
Spinach	0.20	--	0.30	*Tolerance is harmonized to the Canadian MRL*
Tomato subgroup 8-10A	--	0.15	0.30	*Tolerance is harmonized to the Codex MRL set on tomatoes*
Vegetable, cucurbit, group 9	0.40	--	0.50	*Tolerance is harmonized to the Canadian MRL*
Vegetable, legume, edible podded, subgroup 6A	0.60	--	0.80	*Tolerance is harmonized to the Canadian MRL*

[1] The recommended tolerance for wet apple pomace is higher than the proposed tolerance because the value determined is rounded following the OECD rounding convention.
[2] A separate tolerance of 1.5 ppm has been previously established on bifenthrin for mayhaw.

Upon establishment of the recommended tolerances listed above, tolerance listings under §180.442(a) for the following individual crops should be revoked since they will be included in the new crop group and crop subgroup listings: eggplant, grape, groundcherry, okra, pear, pepino, pepper (bell & non-bell), pistachio, strawberry, tomato, and turnip greens. The crop group and subgroup listings for leafy petioles subgroup 4B, *Brassica* head and stem subgroup 5A, *Brassica* leafy greens subgroup 5B, caneberry subgroup 13A, citrus fruit group 10, and tree nut group 14 are also to be removed and replaced by the current crop group definitions as shown in Table 2.1.2. The time-limited tolerances listed under §180.442(b) for apple, avocado, nectarine, peach and pomegranate should also be revoked if permanent tolerances in table 2.1.2 are established based on the Section 3 registrations.

HED also recommends that the following established bifenthrin tolerances be revised to express these limits with the appropriate number of significant figures: bananas at 0.10 ppm, cattle meat at 0.50 ppm, cotton undelinted seed at 0.50 ppm, goat meat at 0.50 ppm, hog meat at 0.50 ppm,

horse meat at 0.50 ppm, sheep meat byproducts at 0.10 ppm, sheep meat at 0.50 ppm, and spinach at 0.20 ppm.

2.1.3 Revisions to Petitioned-For Tolerances

Except for the apple wet pomace, pome fruit and tomato subgroup limits, the tolerances proposed by the petitioner are the same as those which are being recommended. In setting the apple wet pomace tolerance, HED recommends following the OECD rounding rules which would establish a limit of 1.5 ppm for this processed commodity. The tolerances for Fruit, pome, group 11-10, except mayhaw, and tomato subgroup 8-10A are recommended to be set at higher limits than were proposed by the petitioner so that they may be harmonized with the applicable international MRLs. A revised Section F should be submitted so the proposed tolerances are the same as those recommended by HED.

2.1.4 International Harmonization

There are no Canadian, Mexican or Codex MRLs established for the residues of bifenthrin in/on the apple wet pomace, avocado, peach, or pomegranate. International harmonization is not at issue in establishing tolerances for these commodities. Because there is an established Canadian MRL of 0.90 ppm set on pears, HED recommends harmonizing the tolerance determined for pome fruit group 11-10 to the Canadian pear limit. There are established MRLs for tomatoes set by Canada at 0.50 ppm and Codex at 0.30 ppm. For the purpose of international harmonization, HED recommends that the tolerance determined for tomato subgroup 8-10A at 0.15 ppm be raised to the Codex MRL of 0.30 ppm. Because a different pattern of use is proposed with this petition for *Brassica* leafy greens that results in higher residues, the recommended tolerance for this crop grouping cannot be harmonized with established international MRLs. Further review of the established bifenthrin tolerances also finds there are a number of differences between proposed/established U.S. tolerances and Canadian MRLs set on several crops. For the purpose of harmonization, the tolerances should be raised for garden beet roots to 0.50 ppm, brassica head and stem subgroup 5A to 0.90 ppm, mayhaw to 1.5 ppm, spinach to 0.30 ppm, cucurbit vegetable group 9 to 0.50 ppm, and vegetable legume edible podded subgroup 6A to 0.80 ppm. For all other commodities including the requested crop group conversions, these tolerances have all been harmonized with the applicable Canadian and Codex MRLs to the greatest extent possible (see Appendix E).

2.2 Label Recommendations

2.2.1 Residue Chemistry

All bifenthrin labels must be revised to delineate the recommend and crop grouping nomenclature following all the conversions recommended above in Section 2.1.2. The proposed labels should also contain the following revisions:

Proposed Crop Group Conversions

- The Fanfare® 2 SC (EPA Reg. No. 66222-236) and Fanfare® II E (EPA Reg. No. 66222-261) labels should be revised to specify the tomato subgroup designation (tomato

subgroup 8-10A) for the established use on tomatoes. These labels must also be revised to specify the current subgroup 8-10B designation (pepper/eggplant subgroup 8-10B) for the established use on peppers and eggplant. With the establishment of this subgroup, the use directions specified separately for okra are no longer needed since this crop is included in the pepper/eggplant subgroup. These labels also require revision to specify the current 13-07F subgroup (fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F) designation for the established use on grapes which now include the other applicable small vine climbing fruit (except fuzzy kiwifruit). Further, the revision of these labels is also required to specify the current 13-07G subgroup designation (berry, low growing, subgroup 13-07G) for the established use on strawberries which now include the other applicable low growing berries (except cranberry which follows a different use pattern).

- The Brigade® 2 EC (EPA Reg. No. 279-3313), Brigade® WSB (EPA Reg. No. 279-3108), Fanfare® 2 EC (EPA Reg. No. 66222-99), Fanfare® 2 SC (EPA Reg. No. 66222-236), and Fanfare® II E (EPA Reg. No. 66222-261) labels should be revised to specify the current 10-10 crop group designation (fruit, citrus, group 10-10) for the established uses on citrus fruit. In addition, these labels should also be revised to specify the current 14-12 crop group designation (nut, tree, group 14-12) for the established use on tree nuts.

A revised Section B reflecting these changes should be submitted.

2.2.2 Residential Exposure

- HED notes that there are residential post-application scenarios that result in risk estimates of concern where potential mitigation may impact label language.

- The label for EPA Reg. No. 1021-1858, a dust formulation, allows broadcast use on stored products and lawns/turf. A maximum single application rate for some indoor uses is needed in order for these uses to be assessed. This label also includes contradictory information for use on mattresses and bedding ("For use in/on … Mattresses… [and] Bedding", vs. "Do not use product on mattresses… [or] bed linens."

2.2.3 Occupational Exposure

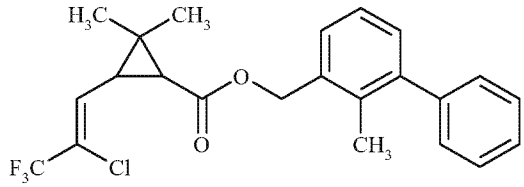
- HED notes that there are several occupational handler scenarios for the registered uses of bifenthrin that may impact potential label language/mitigation. Additionally, several seed treatment scenarios rely on data assuming occupational handlers wear only gloves, which may impact potential label language/mitigation if gloves are not already required on registered labels containing seed treatment uses.

- This risk assessment relies on a 2015 study by the Agricultural Handlers Exposure Task Force (AHETF) that measured dermal and inhalation exposure for workers who mixed and loaded water-soluble packet pesticide products. Commensurate with the behaviors and practices represented by these data, labels for products formulated in water-soluble packaging should incorporate the Agency's revised instructions for proper mixing and

loading of water-soluble packets. This revised language is aimed at ensuring that water-soluble packets are allowed to dissolve in water via mechanical agitation as intended, and prevented from rupturing by streams of water or other means.

3.0 Introduction

3.1 Chemical Identity

Table 3.1. Bifenthrin Nomenclature.	
Chemical structure	
Common name	Bifenthrin
Company experimental name	N/A
IUPAC name	2-methylbiphenyl-3-ylmethyl(Z)-(1RS,3RS)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2dimethylcyclopropanecarboxylate
CAS name	(1R,3R)-rel-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-2,2-dimethyl-cyclopropanecarboxylic acid, (2-methyl[1,1'-biphenyl]-3-yl)methyl ester
CAS registry number	82657-04-3
Proposed End-use product (EUPs)	Brigade® 2 EC; 10% Emulsifiable Concentrate (EPA Reg. No. 279-3313) Brigade® WSB; 10% Wettable Powder (EPA Reg. No. 279-3108) F6216 EW; 10% Emulsion, oil in water (EPA Reg. No. 279-3329) Hero® EW; 11.25% Emulsion, oil in water (EPA Reg. No. 279-3315) Fanfare® 2 EC; 25% Emulsifiable Concentrate (EPA Reg. No. 66222-99) Fanfare® 2 SC; 25% Suspension Concentrate (EPA Reg. No. 66222-236) Fanfare® II E; 25% Emulsifiable Concentrate (EPA Reg. No. 66222-261)

3.2 Physical/Chemical Characteristics

Physiochemical properties for bifenthrin are shown in Appendix B.

Bifenthrin is a pyrethroid insecticide formed as an off-white to pale tan waxy solid, with a very faint, slightly sweet odor. The vapor pressure (1.80×10^{-7} mmHg) suggests that the chemical is expected to be semi-volatile from dry surfaces/soil and the Henry's law constant (7.2×10^{-3} atm-m^3/mol) suggests that it is expected to volatilize from water and wet soil. However, given the fact that bifenthrin adsorbs strongly to soil particles and organic matter, which may reduce volatilization from water and soil surfaces. Bifenthrin has a very low limit of solubility (0.014 µg/L) and, therefore, it is not expected to concentrate in water; however, it is considered to be a persistent pyrethroid in the environment, stable to hydrolysis and slow to biodegrade. Additionally, the $\log K_{OW}$ of $> 1 \times 10^6$ indicates that bifenthrin has the potential to bioaccumulate.

3.3 Pesticide Use Pattern

A summary of the representative registered food end-use products and use sites with the highest application rates or percent ai is provided in Appendix F. A summary of the representative registered non-food/non-crop end use products and use sites with the highest application rates or percent ai is provided in Appendix F.

Existing Uses
A summary of the representative registered EUP labels and use sites was identified by HED and reviewed by the BEAD is provided in Appendix F (Tables F.2 – Table F.4). Table F.2 presents the registered EUPs the Agency has assumed are intended for use by residential handlers (i.e., labels do not mention PPE and labels specify applications in residential areas). Table F.3 summarizes the existing agricultural uses of bifenthrin, and Table F.4 summarizes the non-agricultural occupational uses of bifenthrin.

Labels vary with respect to requirements for work attire and PPE. For example, some labels do not specify any requirements for work attire and have been assessed for residential handlers. Other labels require chemical-resistant gloves, long-sleeve shirt and long pants, and shoes plus socks. Some labels require additional PPE such as protective eyewear, dust/mist respirators, coveralls, and aprons. Those EUPs requiring PPE beyond baseline attire and chemical resistant gloves are co-formulations with other active ingredients. The REI listed on the representative agricultural crop labels is 12 hours.

Proposed Uses
IR-4 has submitted a petition for establishing permanent Section 3 tolerances for bifenthrin on: avocado, *Brassica* leafy subgroup 4-16B, low growing berry subgroup 13-07 G, peach subgroup 12-12B, pepper/eggplant subgroup 8-10B, pome fruit group 11-10 (except mayhaw), pomegranate, small vine climbing subgroup 13-07F, tomato subgroup 8-10A. IR-4 has also proposed crop group conversions for citrus group 10-10, caneberry subgroup 13-07A, and tree nut group 14-12. Some of the proposed commodities and some of the commodities within the proposed crop groups or crop group expansions have existing Section 18 emergency exemption tolerances for bifenthrin (apple, avocado, nectarine, peach, and pomegranate). A summary of the proposed uses is provided in Appendix F (Table F.1).

All proposed labels require occupational handlers to wear baseline attire (long sleeved shirts, long pants, shoes, socks) and chemical resistant gloves; mixer/loaders or others exposed to the concentrate are also required to wear protective eyewear. The REI for the proposed uses of bifenthrin is 12 hours.

3.4 Anticipated Exposure Pathways

Humans may be exposed to bifenthrin in food and drinking water, since bifenthrin may be applied directly to growing crops and application may result in residues of bifenthrin reaching sources of drinking water. Adults and children may be exposed to bifenthrin in residential settings due to the currently registered (existing) uses. Non-occupational bystanders may be exposed to spray drift from occupational applications. Occupational exposures are expected

from the application of bifenthrin and from reentry into previously treated areas. This risk assessment considers the relevant exposure pathways based on all of the proposed and existing uses of bifenthrin.

3.5 Consideration of Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf). As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age and ethnic group. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Spray drift can also potentially result in post-application exposure and it was considered in this analysis. Further considerations are also currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to other types of possible bystander exposures and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

4.0 Hazard Characterization and Dose-Response Assessment

Bifenthrin is a member of the pyrethroid class of insecticides. Pyrethroids have historically been classified into two groups, Type I and Type II, based upon chemical structure and toxicological effects. Type I pyrethroids, which lack an alpha-cyano moiety, induce in rats a syndrome consisting of aggressive sparring, altered sensitivity to external stimuli, hyperthermia, and fine tremor progressing to whole-body tremor and prostration (T-syndrome). Type II pyrethroids, which contain an alpha-cyano moiety, in rats produce a syndrome that includes pawing, burrowing, salivation, hypothermia, and coarse tremors leading to choreoathetosis (CS-syndrome) (Verschoyle and Aldridge 1980; Lawrence and Casida 1982).

Bifenthrin is a Type I synthetic pyrethroid, the only member of the biphenyl-methyl ester class and it is enriched to 98% cis form. The adverse outcome pathway (AOP, based on the Bradford-Hill criteria) shared by pyrethroids involves the ability to interact with voltage-gated sodium channels (VGSCs) in the central and peripheral nervous systems, leading to changes in neuron firing, and ultimately neurotoxicity (see Figure 4.0).

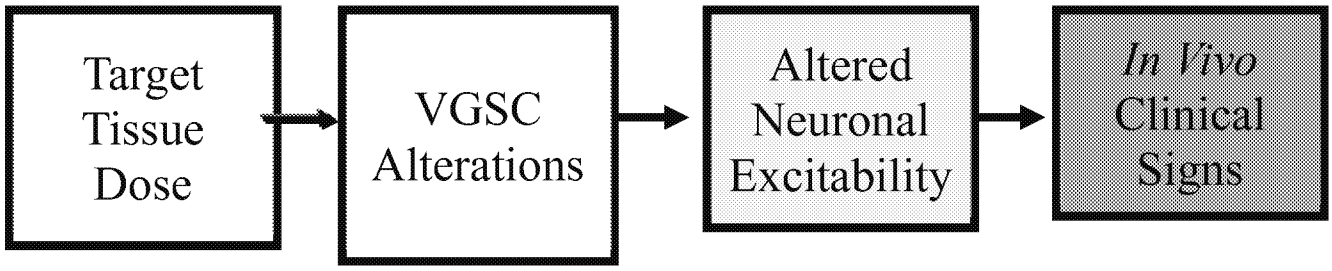


Figure 4.0. Adverse outcome pathway for pyrethroids

Dosing method, vehicle type, and vehicle volume considerably influence the points of departure of the pyrethroids, including bifenthrin (Wolansky et al., 2007). For example, the ED_{50} value (i.e., the effective dose for a 50% decrease) for another pyrethroid, deltamethrin, is 196 times lower using corn oil versus carboxymethylcellulose as the vehicle with gavage dosing, based on motor activity data (Crofton et al., 1995). The vehicle and volume used in gavage dosing vary considerably among pyrethroids thus making quantitative comparisons among them difficult. In the specific case of bifenthrin, decreasing the corn oil volume from 5 mL/kg to 1 mL/kg lowers the ED_{50} value of motor activity by a factor of two (Wolansky, 2007), demonstrating how dosing volume affects toxicity. Furthermore, bolus/gavage dosing results in increased potency of the pyrethroid relative to exposure in feed. In the bifenthrin rat developmental studies, the LOAEL was 1.77 mg/kg/day with corn oil gavage administration while a dietary administration had a LOAEL of 15.5 mg/kg/day (8.8 times higher, with tremors as the common endpoint). The gavage ACN study, which did not use a vehicle of any kind, had a much higher LOAEL of 70.3 mg/kg, based on changes in motor activity, clinical signs and mortality. The Wolansky acute oral rat study was particularly conservative in design and utilized a corn oil vehicle at 1 mL/kg with gavage dosing (POD = 3.1 mg/kg). In perspective, rat feed often does contain some content of vegetable oil, such as corn oil.

4.1 Toxicology Studies Available for Analysis

The database of experimental toxicology studies available for bifenthrin provides a robust characterization of the hazard potential for adults and children ≥ 6 years old. In addition, there are on-going efforts to develop methods to inform the possibility of increased sensitivity to pyrethroids as a class in juvenile rats at doses near the LOAEL values, which is discussed further in Section 4.4. Despite these scientific efforts, HED is confident that it has chosen points of departure and uncertainty factors in this risk assessment which are health protective and have a strong scientific foundation. The bifenthrin database is considered complete for risk assessment. Based on a weight of the evidence (WOE) approach the Hazard and Science Policy Council (HASPOC) recommended that the requirements for a 90-day dermal toxicity study and an immunotoxicity study for bifenthrin be waived at this time (TXR#0056209, 04/26/2012; TXR# 0056729, 08/12/2013).

The data from the following studies were used to evaluate the hazard potential of bifenthrin:

-Wolansky Acute Oral Rat Study

-Nemec/WIL Acute Oral Rat Study
-Acute Neurotoxicity Study (ACN) Rat Study
-Subchronic Neurotoxicity Study (SCN) Rat Study
-Developmental Neurotoxicity (DNT) Rat Study
-21-Day Dermal Rat Study
-21-Day Dermal Rabbit Study
-28 Day Inhalation Rat Study
-90-Day Oral Rat Study
-90-Day Oral Dog Study
-Developmental Rat Studies (Gavage and Dietary)
-Developmental Rabbit Study
-Reproduction Rat Study
-1 Year Dog Study
-Chronic/Cancer Rat Study
-Chronic/Cancer Mouse Study
-Metabolism and Pharmacokinetic Studies

The studies available for consideration of bifenthrin toxicity provide a comprehensive database, with routes of administration which are consistent with potential exposure scenarios. In addition, numerous studies from the scientific literature conducted over several decades describe the pharmacodynamic and pharmacokinetic profile of the pyrethroids in general. This scientific literature has been recently reviewed by several groups (Wolansky and Harrill 2008; Weiner et al. 2009). The non-guideline Wolansky acute oral study in rats measuring locomotor activity provides robust data to evaluate the hazard potential of bifenthrin.

4.2 Toxicological Profile

Bifenthrin has been evaluated for a variety of toxic effects in guideline experimental toxicity studies. Predominantly, behavioral changes characteristic of Type I pyrethroids such as muscle tremors were seen in most of the bifenthrin experimental toxicology studies, consistent with its MOA to activate sodium channels. This observation was noted in several bifenthrin toxicology studies across various species at different durations, and different routes of exposure and life stages. The published acute Wolansky study provided robust data on locomotor activity, due to the fact that it utilized nine dose groups and a benchmark dose data analysis method to address dose spacing effects.

The Wolansky study is considerably conservative, using the most sensitive rat strain, plus gavage dosing utilizing a vehicle and volume producing the most adverse responses (i.e., 1 ml/kg corn oil). Muscle tremors were observed in nearly all experimental studies in all species and durations, however, motor activity was not measured in most of these studies. The decreased locomotor activity observed in the acute Wolansky study was the most sensitive endpoint identified; therefore, was selected as the endpoint for acute dietary and short-term incidental oral risk assessment. In the acute Wolansky study, tremors were not observed at doses less than 8 mg/kg bifenthrin, while decreased motor activity was significant at doses of 4 mg/kg and above. Further, the Wolansky study monitored the toxicology at the time of peak effects, unlike most of the guideline studies. Additional effects seen in one or more studies included: muscle twitching,

decreased grip strength, altered landing foot splay, depressed respiration, increased grooming counts, loss of muscle coordination, staggered gait, exaggerated hind limb flexion, and convulsions at high doses. Decreased body weight and food consumption were also noted in repeat-dosing dietary studies. There was no clear evidence in the database that either gender was more sensitive to bifenthrin. Route-specific dermal and inhalation toxicity studies were utilized to assess dermal and inhalation risks.

Bifenthrin has been evaluated for potential developmental effects in the rat (following gavage and dietary administration) and in the rabbit (gavage administration). Maternal toxicity included neurological effects (tremors in rats and rabbits; head and forelimb twitching in rabbits). There were no developmental effects of biological significance in either species. The registrant submitted a DNT study, which establishes a clear NOAEL for the adult and offspring toxicity. The NOAEL in adults and offspring is similar in magnitude, and the LOAELs are based on the clinical signs of neurotoxicity (dams had tremors and convulsions, offspring had increased grooming counts). Based on targeted testing in the DNT study for common endpoints for bifenthrin, there was no increase in sensitivity in rat pups. However, the Agency has reviewed existing pyrethroid data and concludes that the DNT is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids (E. Scollon, TXR#0056045, D381210, 06/27/2011). Some literature studies indicated susceptibility for other pyrethroids, but in context, these studies were conducted at relatively high doses, which may not reflect environmental exposures (Sheets et al., 1994). The reproductive toxicity of bifenthrin was examined in a two-generation reproduction study in the rat. Tremors were noted only in females of both generations, with one parental generation rat observed to have clonic convulsions, and no observed effects in the offspring. Overall, there is no indication of increased juvenile sensitivity specifically to bifenthrin.

Bifenthrin is classified as a Group C "Possible human carcinogen," based on an increased incidence of urinary bladder tumors in mice. However, EPA concluded that the bladder tumors may not be uncommon in mice and are not likely to be malignant. Additionally, these tumors were observed only in male mice at the highest dose. No evidence of carcinogenicity was observed in bifenthrin carcinogenicity studies in rats, and bifenthrin was negative in five different tests for mutagenicity, but was marginally active in a forward mutation test in mouse lymphoma cells. Overall, based on the available information, there is a low concern for mutagenicity.

With respect to acute lethality testing, bifenthrin has low acute toxicity via the dermal route (Category III) of exposure and a moderate acute toxicity via the oral route (Category II). The combined male-female LC_{50} value for bifenthrin is 1.01 mg/L (Category III), based on an acute inhalation study. It is neither an eye nor skin irritant, nor is it a dermal sensitizer.

4.3 Pyrethroid Pharmacokinetic and Pharmacodynamic Profile

OPP is making the best use of the extensive scientific knowledge about the AOP on pyrethroids in the risk assessments for this class of pesticides. In this way, information on a subset of pyrethroids can be used to help interpret and understand the toxicological profile for other members of the class. In that regard, a group of pesticide registrants and product formulators

known as the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA) has been conducting multiple experiments with permethrin and deltamethrin as models for Type I and Type II compounds, respectively, in order to develop an initial extensive database of *in vitro* and *in vivo* toxicology studies, and highly refined physiologically-based pharmacokinetic (PBPK) models.

In addition to the efforts of the CAPHRA, the extensive body of scientific literature on the pyrethroids provides insight into the contributions of PK and PD to the general toxicity profile of this class of chemicals. This information also provides valuable insight into the potential age-related differences in toxicity for the pyrethroids. This scientific literature has been reviewed by several groups (Soderlund et al. 2002; Shafer et al., 2005; Wolansky and Harrill 2008) and the following sections of the risk assessment discuss the specific issues related to pyrethroid PK, pyrethroid PD, and age-related differences in pyrethroid toxicity. Furthermore, the Agency will be updating its literature review for pyrethroids in 2017 as described below prior to completion of the revised risk assessments.

In recent years, the National Academies' National Research Council (NRC) has encouraged the Agency to move towards systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision making (NRC 2011, 2014). The NRC defines systematic review as "a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies" (NRC 2014). According to the NRC, systematic reviews "have several common elements: transparent and explicitly documented methods, consistent and critical evaluation of all relevant literature, application of a standardized approach for grading the strength of evidence, and clear and consistent summative language." EPA's Office of Chemical Safety and Pollution Prevention is currently developing systematic review policies and procedures. The Agency is currently working with EPA reference librarians to develop a systematic review for the pyrethroids. This analysis is still on-going and will be incorporated in the revised risk assessment for bifenthrin.

4.3.1 Pharmacokinetics

PK can be defined as what the body does to the chemical; in this case, how pyrethroids are distributed and eliminated following exposure. Specific to pyrethroids, PK refers to the process(es) that determine(s) the concentration of the pyrethroids reaching sodium channels. The underlying PK of pyrethroids is an important determination of their toxicity because the concentration of pyrethroid at the sodium channel relates to the extent of toxicity; greater pyrethroid concentration translates as increased neurotoxicity. Physiological processes that significantly contribute to the PK include metabolism, protein binding, and partitioning. Carboxylesterases and cytochrome P450 enzymes are the two major enzyme families responsible for the metabolism of pyrethroids. It is the ontogeny of these enzymes that accounts for the age-related sensitivity observed after pyrethroid exposures, as described below in more detail. In terms of partitioning, pyrethroids tend to distribute into fat. However, pyrethroid residues in fatty tissue are not available to interact with the voltage-gated sodium channels (VGSCs) in vital tissues and, therefore, do not contribute to overall toxicity.

Age-dependent PK differences have been identified for several pyrethroids; that is, there are differences in the ability of adults and juveniles to metabolize pyrethroids. The enzymes that metabolize and detoxify pyrethroids are present in rats and humans at birth (Koukouritaki et al. 2004; Yang et al. 2009). As a result, both juveniles and adults are able to tolerate low doses of pyrethroids when the internal dose, or the amount of pyrethroid at the sodium channel, is low. However, the expression, and therefore activity, of these enzymes increases with age, conveying in adults a greater capacity than juveniles to detoxify pyrethroids (Anand et al. 2006; de Zwart et al. 2008; Yang et al. 2009). For example, the rate of *in vitro* metabolism of deltamethrin by plasma carboxylesterases, plus hepatic carboxylesterases and cytochrome P450s (microsomes) is at least 6 times as high for post-natal day (PND) 90 rats as for PND 10 rats (Anand et al. 2006). In humans, expression of hepatic carboxylesterases is significantly lower in infants <3 weeks old but then increase to near adult levels (Hines et al., 2016). Similar information is also available for the major human P450s involved in pyrethroid metabolism (CYP2C8, CYP2C19, and CYP3A4). CYP2C19 levels are approximately 80% of adult values from >5 months to 10 years, CYP3A4 reaches near adult levels by 1-2 years, and CYP2C8 levels are comparable to adult levels after 6 months of age (Koukouritaki et al., 2004; Stevens et al., 2003; Song et al., 2015). As a consequence, higher internal doses (i.e., those associated with high doses in experimental toxicology studies) overwhelm the clearance mechanisms in juveniles, but because adults have greater enzyme activity, they are able to tolerate higher doses prior to the onset of toxicity. As a matter of perspective, the anticipated exposures from typical dietary or residential activities are not expected to overwhelm the premature metabolic systems in juveniles.

To better understand the role of PK and reduce uncertainty associated with extrapolating across species (i.e., rat to human) and life stages, the Agency developed PBPK models designed to predict pyrethroid concentration in tissues following *in vivo* exposure. The Agency has determined that the important PK properties relevant to the metabolism and distribution of pyrethroids in the body are sufficiently similar for members of this class such that using a 'generic' or family model structure for this class is scientifically appropriate. In other words, because of the similarities in the PK profiles of pyrethroids, a single model structure is able to predict the tissue dose based on the PK of every member of the class. The family modeling approach was primarily developed based on PBPK modeling performed with deltamethrin and was presented to, and supported by, the Federal Insecticide, Fungicide, and Rodenticide Scientific Advisory Panel (FIFRA SAP), (USEPA 2007)[3].

The initial deltamethrin PBPK model presented to the SAP was developed in the adult male Sprague Dawley (SD) rat (Mirfazaelian et al. 2006). The deltamethrin PBPK model was further refined based on oral bioavailability and disposition studies in rats and included estimates for target tissue concentrations in humans (Godin et al. 2010). The initial PBPK model was also extended by accounting for age-dependent changes in physiological and biochemical parameters (Tornero-Velez et al. 2010) to address juvenile sensitivity in rats. This model predicts that, compared to adult rats (i.e., 90-days old), equivalent brain concentrations of deltamethrin would be achieved with a 3.8x fold lower oral dose in 10-day old rats and 2.5x lower dose in 21-day old rats. For example, the internal dose from an administered dose of 1 mg/kg in the adult is equivalent to the internal dose from an administered dose of 0.26 mg/kg (≈1 mg/kg÷3.8mg/kg) in

[3] Supporting materials and meeting minutes can be accessed at the public docket (www.regulations.gov) at Docket ID EPA-HQ-OPP-2007-0388

the 10-day old rat and to an administered dose of 0.4 mg/kg (≈1 mg/kg÷2.5mg/kg) in the 21-day old rat. As a result, the Agency concludes that juvenile rats are three times as sensitive as adult rats with respect to pyrethroid PK. At this time, the Agency considers that the differences in the PK profile observed in the rat are relevant to humans. Therefore, the PK contribution to the FQPA Safety Factor is 3X for children less than 6 years old and 1X for children 6 years of age or older and for adults. Further information regarding the decision to retain the FQPA Safety Factor and the choice of age groups it applies to can be found in the Re-Evaluation of the FQPA Safety Factor of Pyrethroid Pesticides memo (D381210, TXR#0056045, E. Scollon, 6/27/2011).

Currently, the CAPHRA is collecting metabolism and tissue dosimetry data from rats and human tissues across different life stages. These data will be used to inform the development of PBPK models for the pyrethroids. The CAPHRA presented its most recent experimental data and proposed path forward to the SAP on May19th 2015 (USEPA 2015)[4]. Based on the comments from the SAP, the CAPHRA continues to pursue its research efforts and gather additional data.

Following oral administration, bifenthrin was absorbed and eliminated primarily in the feces (about 70% within 48 hours) (MRID Nos. 00163066 and 00163067). Nearly all (91 – 92%)parent compound and/or metabolites are excreted in either urine or feces within 7 days (MRID 00163066). The highest level of radioactivity was detected in fat. Following a single oral dose of 4 mg/kg radio-labeled bifenthrin in corn oil, radioactivity in blood plasma peaked at 4 hours (MRID 00163069). An oral absorption half-life of 1.5 hours (with a lag-time of a 0.5 hour following first order kinetics) has been calculated for bifenthrin at 4 mg/kg dosing. In blood, bifenthrin residues have a half-life of approximately 10 hours (see Figure 4.3.1) with 17% of the residues (compared to peak values) remained 24 hours post-dosing and only 8% of the peak radioactive residues remained in the serum at 72 hours (Selim 1986; MRID 00163069; MRID 00163070). Similar kinetics were observed in rats given 35 mg/kg, although the peak plasma levels were slightly delayed to 6 hours (Selim 1986).

In a bioaccumulation study with rats orally dosed with 0.5 mg/kg/day for up to 70 days, fat and skin tended to accumulate parent bifenthrin to a much greater extent than other tissues with half-lives of 51 and 50 days, respectively [Joint Meeting on Pesticide Residues (JMPR) Report, 2009[5]; MRID 00163070]. The estimated half-lives were 19 days for liver and 28 days for kidneys.

The major route of bifenthrin metabolism is hydrolysis of the ester linkage with oxidation of the resulting alcohol to the acid form (MRID 00163069).

[4] Docket ID EPA-HQ-OPP-2015-0130
[5] http://www.inchem.org/documents/jmpr/jmpmono/v2009pr01.pdf

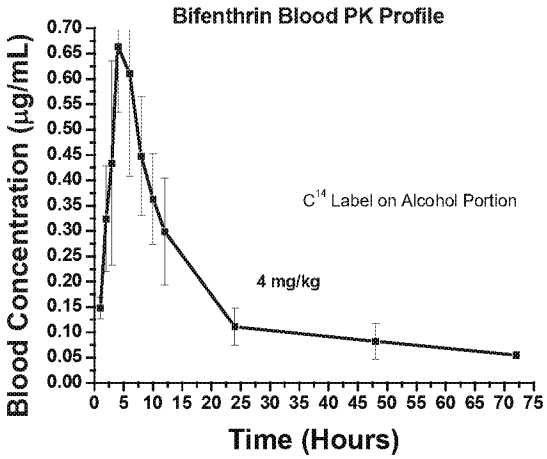


Figure 4.3.1. Pharmacokinetic profile of radiolabeled-bifenthrin in rat plasma following a single oral dose of 4 mg/kg in corn oil. Bifenthrin blood concentration is based on radioactivity and, therefore, represents a total of parent and metabolic products (Selim 1986, MRID 00163069).

4.3.2 Pharmacodynamics

PD can be defined as the changes that chemicals cause to the body, in this case, how pyrethroids interact with the sodium channels. Substantial evidence from *in vitro* and *in vivo* studies support the AOP illustrated in Figure 4.0 and the disruption of sodium channels by pyrethroids as an early key event (Lund and Narahashi 1982; Salgado et al. 1989; Song and Narahashi 1996; Tabarean and Narahashi 1998; Soderlund et al. 2002).

There are several studies that provide specific information for bifenthrin. Choi and Soderlund (2006) examined interactions of several pyrethroids with mammalian VGSCs expressed in *Xenopus* oocytes. With respect to altered neuronal excitability, Type I pyrethroids cause slight prolongations of the sodium current tails (e.g. ~20 ms), often resulting in long trains of action potentials. In contrast, Type II pyrethroids significantly prolong sodium tail currents (e.g. 200ms to minutes) typically resulting in increased resting membrane potential and ultimately causing depolarization-dependent action potential block. Figure 4.3.2 confirms the effects of bifenthrin to increase sodium channel currents in rat $NaV_{1.8}$ channels expressed in *Xenopus* oocytes.

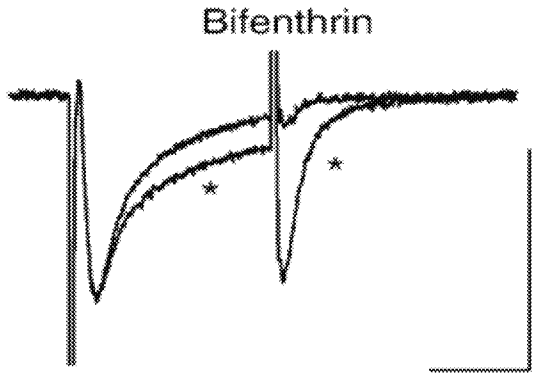


Figure 4.3.2. Resting modification of rat Nav1.8 sodium channels by bifenthrin, expressed in xenopus oocytes. Channel current vs time traces from individual representative oocytes in the absence or presence (*) of 100 µM bifenthrin were obtained during and after 40-ms depolarizations from 100 mV to 10 mV. Calibration bars: 20 ms for the x-axis and 500 nAmp on the y-axis. Data extracted from Figure 3 in Choi and Soderlund (2006).

HED would prefer to use an early key event in the AOP for pyrethroids in selection of points of departure, such as sodium channel modification. However, *in vivo* techniques used to detect VGSC alteration and altered neuronal excitability are not practical for use in risk assessment at this time and approaches for extrapolating *in vitro* findings to *in vivo* measures are not yet developed. As such, the Agency is focusing its efforts for all pyrethroids in hazard characterization and identification on the apical endpoint (i.e., changes in neurobehavior in laboratory animals). Neurotoxicity resulting from pyrethroids is generally characterized by tremors, hyper- or hypothermia, altered response to stimuli, salivation, reduced locomotor activity or convulsions (Nemec 2006; Wolansky and Harrill 2008; Breckenridge et al. 2009). In addition, results from a study by Wolansky et al. (2006) indicated that motor activity is a sensitive and robust measure of neurotoxicity for this class of compounds. The changes in motor activity observed were not specific to either of the syndromes described for pyrethroids and were observed with both Type I and Type II pyrethroids.

In contrast to the age-related PK differences identified in the 2011 analysis, PD contributions to pyrethroid toxicity are not age-dependent even though there are several variations of sodium channels, called isoforms, which are differentially expressed by tissue and age. Due to the nature of the interaction of pyrethroids with sodium channels, it is difficult to obtain dynamic information *in vivo*. To date, a readily useable biomarker of *in vivo* pyrethroid interaction with sodium channels has not been identified, making it impractical to determine the isoform combinations that are present and being modulated by pyrethroids. Therefore, much of the information available to the Agency to characterize the PD relationship between pyrethroids and sodium channels has been derived from *in vitro* studies using frog oocytes or neuronal cells cultured in defined media. These *in vitro* techniques do not provide direct quantitative measure of *in vivo* pyrethroid activity. However, these techniques consistently and qualitatively demonstrate that channel isoforms expressed in juveniles are not more sensitive to pyrethroid perturbation compared to isoforms expressed in adults and that, pharmacodynamically, the rat is a conservative model for humans. For example, Meacham et al. (2008), compared the sensitivity

of an adult isoform and a juvenile isoform expressed in frog oocytes to deltamethrin. The isoforms had comparable responses at environmentally relevant concentrations (< 500 nM) of deltamethrin, suggesting a lack of PD difference between juveniles and adults at low exposure levels. In addition, in a direct comparison of a homologous rat and human VGSC isoform, $NaV_{1.3}$, revealed that the rat isoform was 4-fold more sensitive than the equivalent human sodium channel to the pyrethroid tefluthrin (Tan and Soderlund 2009). These data suggest that the rat is a highly-sensitive model and extrapolations from the rat would be protective of human health. The occurrence and ontogeny of voltage-gated sodium channels in humans is not well characterized compared to the rat. However, based on the comparable function and distribution of sodium channels between the species, the rat is an appropriate surrogate for the evaluation of human PD (Goldin et al. 2000; Goldin 2002). As a result, the Agency concludes that juvenile rats are not more sensitive than adults with respect to pyrethroid pharmacodynamics. Therefore, the pharmacodynamic contribution to the FQPA SF will be 1X.

4.3.3 Critical Durations of Exposure

One of the key elements in risk assessment is the appropriate integration of temporality between the exposure and hazard assessments. Following a single oral gavage dose, bifenthrin is absorbed rapidly in rats; quickly displaying decreased motor activity and increased tremors. Toxicity is observed as quickly as 1 hour, peaks at 4 hours, and motor activity starts to increase at 7 hours, approximately following the blood PK profile (Wolansky, 2007). Tremors are absent at 12 hours, and rats typically recover within 24 hours without any persisting neurotoxic effects, at doses near the LOAEL value. The toxicity profiles for other pyrethroids are generally similar, and marked by rapid absorption, metabolism, and time-to-peak effect. Consistent with the mode of action, in general, onset of neurotoxicity following an acute pyrethroid dose is rapid, with a time to peak effect for neurobehavioral effects ranging from 4 to 8 hours (Wolansky and Harrill 2008; Weiner et al., 2009; Scollon et al., 2011). Furthermore, rapid metabolism and elimination preclude accumulation and increased potency following repeated dosing. Therefore, for most pyrethroids, the acute toxicity studies typically result in neurotoxicity at lower doses compared to dietary studies that generally result in reduced toxicity at similar doses. The oral NOAELs and LOAELs for tremors established from results of experimental toxicity studies with bifenthrin are remarkably consistent across durations of exposure, ranging from a single dose up to two-years of dosing (see Table 4.3.3). The BMD values from the motor activity results from the Wolansky study are similar to the NOAEL/LOAEL values from the tremor endpoint.

Table 4.3.3. Bifenthrin Oral NOAEL and LOAEL Values Versus Treatment Time.

Study	Duration	Study findings	
Wolansky et al (2006) – rat	Acute, single exposure	BMDL=3.1	BMD=4.1
Developmental neurotoxicity - rat	86 days	NOAEL = 3.6	LOAEL = 7.2
Subchronic oral – dog	90 days	NOAEL = 2.21	LOAEL= 4.42
Subchronic oral – rat	90 days	NOAEL = 3.8	LOAEL = 7.5
Subchronic neurotoxicity - rat	90 days	NOAEL = 2.9	LOAEL = 6.0
Reproductive oral toxicity - rat	120 days	NOAEL = 3.0	LOAEL = 5.0
Chronic-carcinogenicity - mouse	87 weeks	NOAEL = 6.7	LOAEL = 25.6
Chronic-carcinogenicity - rat	2 years	NOAEL = 3.0	LOAEL = 6.1

Comparing the NOAELs and LOAELs established from bifenthrin single oral dose and repeat oral dosing studies, it is apparent that repeat exposures do not result in lower NOAELs, within

the variability of animal testing and body weight scaling corrections. The human equivalent doses for bifenthrin between the dog study and rat study are similar when normalized by body weight. The human equivalent dose for the 90-day dog study NOAEL is 1.35 mg/kg and the value for the acute Wolansky rat study BMDL is similar at 0.90 mg/kg (see Appendix A.4). These data are consistent with the general kinetic profile for bifenthrin. The acute Wolansky study endpoint of decreased motor activity at 4.1 mg/kg ($BMDL_{1SD}$ value of 3.1 mg/kg) is slightly lower than the chronic two-year cancer study LOAEL of 6.1 mg/kg/day. Therefore, the endpoint from the acute study is protective of the endpoints from the repeat dosing studies. Thus, for purposes of endpoint selection and exposure assessment, only single-day risk assessments need to be conducted.

4.4 Safety Factor for Infants and Children (FQPA Safety Factor)[6]

There was no evidence that bifenthrin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

After reviewing the extensive body of peer-reviewed literature on pyrethroids, the Agency has no residual uncertainties regarding age-related sensitivity for women of child bearing age as well as for all adult populations and children ≥6 years of age, based on the absence of pre-natal sensitivity observed in 76 guideline studies for 24 pyrethroids and the scientific literature. Additionally, no evidence of increased quantitative or qualitative susceptibility was seen in the pyrethroid scientific literature related to PD. The Agency is retaining a 3X FQPA SF to protect for exposures of children <6 years of age based on the increased quantitative susceptibility seen in studies on pyrethroid PKs and the increased quantitative juvenile susceptibility observed in high dose studies in the literature. There is no residual uncertainty in the exposure database because adequate non-occupational exposure, consumption, and dietary residue data are available.

4.4.1 Completeness of the Toxicology Database

The toxicology database for bifenthrin is complete. Acceptable developmental toxicity studies in rats and rabbits are available for bifenthrin, in addition to an acceptable reproduction study in rats. The main endpoint for bifenthrin is tremors, a common sign for a pyrethroid, which was detected in most toxicology studies, plus observed during targeted testing in the ACN, SCN and developmental neurotoxicity (DNT) studies. An immunotoxicity study is not required for bifenthrin (U. Habiba, TXR# 0056830, 11/13/2013). At this time, the EPA lacks additional data to address the potential for juvenile sensitivity to many pyrethroids, including bifenthrin.

The Agency is expecting additional *in vitro* and *in vivo* data. In 2010, the Agency requested proposals for study protocols that could identify and quantify potential juvenile sensitivity and received a single response from the Pyrethrin and Pyrethroids Technical Working Group (PPTWG), a conglomerate of pyrethroid registrants. The PPTWG protocol was reviewed during

[6] HED's standard toxicological, exposure, and risk assessment approaches are consistent with the requirements of EPA's children's environmental health policy (https://www.epa.gov/children/epas-policy-evaluating-risk-children).

a July 2010 FIFRA SAP meeting. Based on comments from the SAP, the initial study proposal was refined, and the CAPHRA submitted its updated research to the SAP on May19th 2015 (USEPA 2015). Based on the SAP's most recent comments, the CAPHRA is continuing to: 1) develop rat and human PBPK models, including additional PK data, and 2) conduct *in vivo* behavioral testing using auditory startle testing in rats and plans to submit additional data to the Agency.

4.4.2 Evidence of Neurotoxicity

There are no residual uncertainties with regard to evidence of neurotoxicity for bifenthrin. As with other pyrethroids, bifenthrin causes toxicity from interaction with sodium channels leading to clinical signs of neurotoxicity. These effects are well characterized and adequately assessed by the available guideline and non-guideline studies.

4.4.3 Evidence of Sensitivity/Susceptibility in the Developing or Young Animal

Evidence of increased qualitative or quantitative susceptibility of offspring was not observed in any of the available guideline toxicity studies for bifenthrin.

High-dose studies in the scientific literature indicated that younger animals were more susceptible to the toxicity of pyrethroids. For example, Sheets et al. (1994) found increased brain deltamethrin levels in young rats (PND 11 and 21) relative to adult rats (PND 72). These age-related differences in toxicity are principally due to age-dependent pharmacokinetics; the activity of enzymes associated with the metabolism of pyrethroids increases with age (Anand et al., 2006). However, in context, normal dietary or residential exposures to juveniles are not expected to overwhelm their ability metabolize pyrethroids. In support, at a dose of 4.0 mg/kg deltamethrin (near the Wolansky study LOAEL value of 3.0 mg/kg for deltamethrin), the change in the acoustic startle response was similar between adult and young rats (Sheets, 1994). In addition, the Office of Research and Development (ORD) has recently developed an age-dependent PBPK model for deltamethrin (Tornero-Velez et al., 2010) which predicts a 3–fold increase of pyrethroid in neuronal tissue in younger animals compared to adults. There are several studies (*in vitro* and *in vivo*) that indicate pharmacodynamic contributions to pyrethroid toxicity are not age-dependent. Examination of specific VGSCs have demonstrated that there is a lack of increased sensitivity in either juvenile specific isoforms (Meacham et al., 2008) or in human isoforms compared to rat variants (Tan and Soderlund, 2009).

After reviewing the extensive body of peer-reviewed literature on pyrethroids, the Agency has no residual uncertainties regarding age-related sensitivity for women of child bearing age as well as for all adult populations and children ≥ 6 years of age, based on the absence of pre-natal sensitivity observed in 76 guideline studies for 24 pyrethroids and the scientific literature. Additionally, no evidence of increased quantitative or qualitative susceptibility was seen in the pyrethroid scientific literature related to PD. The Agency is retaining a 3X FQPA Safety Factor to protect for exposures of children < 6 years of age based on the increased quantitative susceptibility seen in studies on pyrethroid PK and the increased quantitative juvenile susceptibility observed in high dose studies in the literature.

4.4.4 Residual Uncertainty in the Exposure Database

There are no residual uncertainties in the bifenthrin database in regard to dietary (food and drinking water), and residential exposures. Although the acute dietary exposure estimates are refined, HED does not believe that the exposure estimates under-estimate risk for the established or proposed uses of bifenthrin. The reason is the residue levels used are based on either monitoring data reflecting actual residues found in the food supply, or on high-end residues from field trials which reflect the use patterns which would result in the highest residues in foods. The residue data used for dietary exposure assessment are described in Section 5.4.1 of this document. Furthermore, processing factors used were either those measured in processing studies, or default high-end factors representing the maximum concentration of residue into a processed commodity. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bifenthrin in drinking water. Additionally, exposure to residential handlers, as well as post-application exposure of adults and children, are based on conservative, health-protective assumptions that also ensure exposures are not underestimated. These assessments will not underestimate the exposure and risks posed by bifenthrin.

4.5 Toxicity Endpoint and Point of Departure Selections

4.5.1 Dose Response Assessment

The details for selecting toxicity endpoints and PODs for various exposure scenarios are presented in Appendix A.2. Based on the proposed and existing use patterns for bifenthrin, dietary, dermal, inhalation, and incidental oral exposures are expected. Bifenthrin does not increase in toxicity with repeated dosing; therefore, acute/single day PODs are protective of longer durations. As such, only single day/acute endpoints/PODs have been selected for bifenthrin.

As previously indicated, the toxicity endpoints in the bifenthrin database are consistently based on clinical signs of neurotoxicity, more specifically tremors. These studies include multiple species, study designs, and durations. Moreover, the acute exposure, or bolus dosing, studies generally result in lower NOAELs compared to longer-term dietary administration studies, consistent with other pyrethroids in this class. Because uncertainty associated with the POD is propagated throughout the risk assessment, one of the key factors in POD selection is the robustness of the dose-response data. The guideline experimental toxicology studies available for bifenthrin are generally high quality and were considered in the POD selection process (Appendix A.2) and in the weight of the evidence evaluation. In addition to the typical guideline studies, data from two special studies (Wolansky study on locomotor activity and Nemec/WIL FOB study) evaluating neurobehavioral outcomes are available for bifenthrin (Nemec 2006; Wolansky et al. 2006). Wolansky et al. (2006) individually measured locomotor activity at the time of peak effect after exposure to 11 pyrethroids, including bifenthrin. Dose-response relationships were determined using 6-11 doses per pyrethroid (9 doses used for bifenthrin) and 3-18 rats per dose group (8-12 animals/group used for bifenthrin), minimizing variability and increasing the confidence in the benchmark dose estimates derived from this study. The locomotor activity for bifenthrin had an excellent dose response. Locomotor activity is an

objective toxicity metric, since it is recorded by photoelectric detectors. Moreover, each pyrethroid was evaluated by the same scientist, thus decreasing some of the variability associated with neurobehavioral measures. In the Nemec/WIL study, 17 pyrethroids were evaluated using a specially designed Functional Observational Battery (FOB) study focused on the outcomes associated with pyrethroid toxicity syndromes. The bifenthrin dose selection in the Nemec/WIL study (Nemec 2006) was sub-optimal (i.e., only 2 doses and too close together), resulting in a poor dose response curve and low confidence of the calculated BMDL value, and was therefore not chosen as a risk assessment endpoint for bifenthrin.

Observation of tremors is the most prominent finding in the guideline experimental toxicology studies, and was considered in the POD determination. Unlike the Wolansky study, guideline studies typically have only three treatment groups and often do not evaluate clinical signs at the time of peak effect. Moreover, scoring metrics of tremors varies widely among guideline studies.

The Wolansky study utilized a rat strain sensitive to neurotoxins (Long Evans), and measured an objective apical endpoint of locomotor activity as the toxicity metric. The BMD_{1SD} value was 4.1 mg/kg at a 20% decrease in locomotor activity and the $BMDL_{1SD}$ value was 3.1 mg/kg. The Wolansky study was considerably conservative, using gavage dosing with a vehicle and volume producing the most adverse responses (i.e., 1 ml/kg corn oil). The BMD data analysis was utilized as a standardized method to address concerns of dose selection and dose spacing. The POD from the Wolansky study is supported by similar NOAEL values in multiple other guideline studies (see Table 4.3.3). Given the multiple strengths associated with study design of Wolansky et al. (2006) and the resulting well-defined dose-response curve, this study provides the most robust data set for extrapolating risk from bifenthrin. The ACN is often considered for acute endpoints. However, the ACN study for bifenthrin did not utilize a vehicle and had an atypical LOAEL value of 70.3 mg/kg. Further, there were deaths at the LOAEL value and, therefore, this is not a sensitive study for the selection of a point of departure.

Acute Dietary (All Age Groups): Quantitation of the dietary risks and episodic granular ingestion risks were performed using the acute oral Wolansky study, with a $BMDL_{1SD}$ value of 3.1 mg/kg and a BMD_{1SD} value of 4.1 mg/kg based on decreased locomotor activity. When assessing acute dietary exposures for adults and children ≥ 6 years, a total uncertainty factor of 100 (10X interspecies, 10X intraspecies, 1X FQPA) was used. When assessing acute dietary and episodic granular ingestion (residential) exposures for children < 6 years old, a total uncertainty factor of 300 (10X interspecies, 10X intraspecies, 3X for FQPA) was used.

Short-term Dermal: Quantification of dermal risks was performed using a 21-day dermal rat study with a $BMDL_{10}$ value of 96.3 mg/kg/day and a BMD_{10} value of 187.0 mg/kg/day based on exaggerated hind limb flexion (see Appendix A.3 for the BMD analysis). When assessing residential exposures for adults and children ≥ 6 years and occupational exposures for adults, a total uncertainty factor of 100 (10X interspecies, 10X intraspecies, 1X FQPA (for residential exposures only)) was used. When assessing residential exposures for children < 6 years old, a total uncertainty factor of 300 (10X interspecies, 10X intraspecies, 3X for FQPA) was used.

Short-term Incidental Oral: Quantitation of the incidental oral risks was performed using the acute oral Wolansky study, with a $BMDL_{1SD}$ value of 3.1 mg/kg and a BMD_{1SD} value of 4.1 mg/kg based on decreased locomotor activity. When assessing incidental oral exposures, a total uncertainty factor of 300 (10x interspecies, 10x intraspecies, 3X for FQPA) was used and follows the same rationale as described for acute dietary.

Short-term Inhalation: Short-term inhalation endpoints for risk assessment were selected from the route-specific 28-day inhalation toxicity study in rats with a LOAEL of 0.0196 mg/L/day based on tremors and increased respiration rate. The NOAEL was 0.0059 mg/L/day. HECs/human equivalent doses for residential (Table 4.5.4.1) and occupational scenarios were calculated (Table 4.5.4.2) on the basis of observed effects (tremors and increased respiration rate). The HECs were derived using the NOAEL and the regional deposited-dose ratio (RDDR). The RDDR accounts for the particulate diameter [mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD)] and estimates the different dose fractions deposited along the respiratory tract. The RDDR also accounts for interspecies differences in ventilation and respiratory tract surface areas. For the 28-day inhalation toxicity study with bifenthrin, an RDDR was estimated at 2.517 based on the effects (tremors and increased respiration rate) seen at the NOAEL of 0.0059 mg/L/day, with a MMAD of 2.40 μm and GSD of 3.81. Human equivalent doses were subsequently calculated from the HECs for residential and occupational handler scenarios.

When assessing residential and occupational inhalation exposures for adults and occupational inhalation exposures for adults, a total uncertainty factor of 30 (3X interspecies, 10X intraspecies, 1X FQPA (for residential exposures only)) was used. The standard interspecies extrapolation UF is reduced from 10X to 3X due to the calculation of HECs accounting for pharmacokinetic (not pharmacodynamic) interspecies differences. For intraspecies variation, 10X is applied. There are no inhalation exposures expected for children < 6 years old. Short-term and intermediate-term (for occupational) exposures are expected; however, bifenthrin does not increase in toxicity with repeated dosing. As such, only single day exposures were assessed.

4.5.2 Recommendation for Combining Routes of Exposure for Risk Assessment

HED combines risk values resulting from separate routes of exposure when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population, and if the hazard associated with the points of departure is similar across routes. A common toxicological endpoint, neurotoxicity, exists for dermal, incidental oral, and inhalation routes of exposure to bifenthrin. Therefore, these were combined for all exposure scenarios assessed, when applicable.

4.5.3 Cancer Classification and Risk Assessment Recommendations

Bifenthrin is classified as a Group C "Possible human carcinogen," based on an increased incidence of urinary bladder tumors in mice (TXR#0051809. Carcinogenicity Peer Review Committee meeting on bifenthrin, Jan. 22, 1992). The classification was based on the following weight of evidence considerations:

- There was a statistically significant dose-related trend in bladder tumors at the high dose. HED concluded that the observed bladder tumors may not be uncommon in Swiss Webster mice and not likely to be malignant. Additionally, these tumors were observed in only one species (mice), in only one sex (male), at only the highest dose (TXR#0051809. Carcinogenicity Peer Review Committee meeting on bifenthrin, Jan. 22, 1992).
- There was a statistically significant dose-related trend for combined hepatocellular adenomas and carcinomas in male mice; however, there was no statistical significance in pairwise comparison.
- There was a statistically significant increase in pairwise comparison for lung tumors, but there was no dose response. Additionally, there was no dose-related trend. There was also no indication that tumor formation occurred early in the mouse carcinogenicity study.
- Bifenthrin was negative in five different tests for mutagenicity, but it was marginally active in a forward mutation test in mouse lymphoma cells. Overall, based on the available information, there is a low concern for mutagenicity.
- No evidence of carcinogenicity was observed in carcinogenicity studies in rats with bifenthrin.

Taking into account all of this information, the Agency has determined the acute endpoint/POD will adequately account for all toxicity, including carcinogenicity that could result from exposure to bifenthrin. While the Agency would typically use a chronic population-adjusted dose (cPAD) to protect for cancer concerns, use of the aPAD is protective for bifenthrin because increasing toxicity with increasing duration of exposure is not seen for bifenthrin. The NOAEL observed in the mouse chronic study, in which tumors were observed, is 6.7 mg/kg/day, 2-fold higher than the POD used for acute risk assessment. The NOAEL in the study was based on tremors seen at the LOAEL of 25.6 mg/kg/day; however, the tumors were observed at 81.3 mg/kg/day, a dose that is 26-fold higher than the current acute POD.

4.5.4 Points of Departure and Toxicity Endpoints Used in Human Health Risk Assessment

Table 4.5.4.1. Summary of Toxicological Doses and Endpoints for Bifenthrin Non-Occupational Assessment.

Exposure Scenario	Point of Departure	Uncertainty/FQPA* Safety Factors	LOC	Study and Toxicological Effects
Acute Dietary (< 6 years old)	$BMDL_{1SD}$= 3.1 mg/kg	UF_A = 10X UF_H = 10X FQPA SF = 3X	aRfD = 0.031 mg/kg/day aPAD = 0.010 mg/kg/day	Wolansky et al. (2006) in rat. BMD_{1SD} = 4.1 mg/kg based on reductions in locomotor activity; Supported by multiple guideline studies
Acute Dietary- (≥ 6 years old)	$BMDL_{1SD}$ = 3.1 mg/kg	UF_A = 10X UF_H = 10X FQPA SF = 1X	aPAD = aRfD = 0.031 mg/kg/day	Wolansky et al. (2006) in rat. BMD_{1SD} = 4.1 mg/kg based on reductions in locomotor activity; Supported by multiple guideline studies
Short-Term (1-30 days) Incidental Oral (< 6 years old)	$BMDL_{1SD}$ = 3.1 mg/kg	UF_A = 10X UF_H = 10X FQPA SF = 3X	LOC = 300	Wolansky et al. (2006) in rat. BMD_{1SD} = 4.1 mg/kg based on reductions in locomotor activity; Supported by

Table 4.5.4.1. Summary of Toxicological Doses and Endpoints for Bifenthrin Non-Occupational Assessment.				
Exposure Scenario	**Point of Departure**	**Uncertainty/FQPA* Safety Factors**	**LOC**	**Study and Toxicological Effects**
				multiple guideline studies
Short-Term (1-30 days) Oral (≥ 6 years old)	$BMDL_{1SD}$ = 3.1 mg/kg	UF_A = 10X UF_H = 10X FQPA SF = 3X	LOC = 300	Wolansky et al. (2006) in rat. BMD_{1SD} = 4.1 mg/kg based on reductions in locomotor activity; Supported by multiple guideline studies
Short-Term (1-30 days) Dermal (< 6 years old)	$BMDL_{10}$=96.3 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 3X	LOC = 300	21-day dermal study in rats. BMD_{10}=187.0 mg/kg/day, based on exaggerated hind limb flexion
Short-Term (1-30 days) Dermal (≥ 6 years old)	$BMDL_{10}$=96.3 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC = 300	21-day dermal study in rats. BMD_{10}=187.0 mg/kg/day, based on exaggerated hind limb flexion
Short-Term (1-30 days) Inhalation (≥ 6 years old)**	NOAEL = 0.0059 mg/L/day HEC = 0.015 mg/L/day (residential handler) Human Equivalent Dose = 0.35 mg/kg/day (residential handler)	UF_A = 3X UF_H = 10X FQPA SF = 1X	LOC = 30	Subchronic inhalation toxicity study MRID 49462201 LOAEL = 0.0196 mg/L/day, based on tremors and increased respiration rate.
Cancer (oral, dermal, inhalation)	**Classification: Category C** (possible human carcinogen). The acute endpoint/POD is considered protective for any potential carcinogenic effects. (TXR#0051809. Carcinogenicity Peer Review Committee meeting on bifenthrin, Jan. 22, 1992).			

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern. N/A = not applicable. HEC = human equivalent concentration.
* FQPA SF is composed of the 3X factor for increased quantitative susceptibility (See Section 4.3.2).
** Residential inhalation exposures are not expected for children < 6 years old based on the proposed and existing uses of bifenthrin.

Table 4.5.4.2. Summary of Toxicological Doses and Endpoints for Bifenthrin Occupational Assessment.				
Exposure Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**LOC**	**Study and Toxicological Effects**
Short-Term (1-30 days) Dermal	$BMDL_{10}$=96.3 mg/kg/day	UF_A = 10X UF_H = 10X	LOC =100	21-day dermal study in rats. BMD_{10}=187.0 mg/kg/day, based on exaggerated hind limb flexion

Table 4.5.4.2. Summary of Toxicological Doses and Endpoints for Bifenthrin Occupational Assessment.				
Exposure Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**LOC**	**Study and Toxicological Effects**
Short-Term (1-30 days) Inhalation	NOAEL = 0.0059 mg/L/day HEC = 0.011 mg/L/day (occupational handler) Human Equivalent Dose = 1.05 mg/kg/day (occupational handler)	UF_A = 3X UF_H = 10X	LOC = 30	Subchronic inhalation toxicity study MRID 49462201 LOAEL = 0.0196 mg/L/day, based on tremors and increased respiration rate.
Cancer (oral, dermal, inhalation)	**Classification: Category C** (possible human carcinogen). The acute endpoint/POD is considered protective for any potential carcinogenic effects. (TXR#0051809. Carcinogenicity Peer Review Committee meeting on bifenthrin, Jan. 22, 1992).			

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern. N/A = not applicable. HEC = human equivalent concentration; HED = human equivalent dose.

Table 4.5.4.3. Summary of HEC/HED Values for Bifenthrin						
Population	**Scenario**	**Toxicity duration adjustment[1]**		**HEC**		**Human Equivalent Dose (mg/kg-day)**
		Daily	Weekly	mg/L	mg/m^3	
Occupational	Handler	0.75	1	0.011	11.0	1.05
Residential	Handler	NA	NA	0.015	15.0	0.35

HEC = human equivalent concentration; NA = not applicable (the expected duration of the exposure scenario is less than the duration in the available inhalation toxicity studies; downward adjustments are not performed).
1 Duration adjustment: Daily adjustment = 8-hour human exposure/6-hour rat exposure = 0.75; Weekly adjustment = 5 days human exposure/5 days rat exposure = 1.

4.6 Endocrine Disruptor Screening Program

As required by FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of registration review for bifenthrin, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), bifenthrin is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required

determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[7] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

Bifenthrin is on List 1 for which EPA has received all of the required Tier 1 assay data. The Agency has reviewed all of the assay data received for the appropriate List 1 chemicals and the conclusions of those reviews are in the chemical-specific public dockets (see Docket EPA-HQ-OPP-2010-0384 for bifenthrin). For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[8]

5.0 Dietary Exposure and Risk Assessment

5.1 Residues of Concern Summary and Rationale

The residues of concern for dietary risk assessment and tolerance expression are summarized below in Table 5.1. The Metabolism Committee determined that only the bifenthrin parent compound [(2-methyl[1,1-biphenyl]3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropanecarboxylate] is the relevant residue of concern for both tolerance enforcement and risk assessment (Metabolism Committee Meeting Minutes, M. T. Flood, 07/27/1993). The nature of the residue in rotational crops is also adequately understood. Based on a confined rotational crop study, HED has concluded that the residue of concern in rotational crops is the parent compound only.

Table 5.1. Summary of Residues of Concern to be Included in the Risk Assessment and Tolerance Expression.

Matrix		Residues Included in Risk Assessment	Residues Included in Tolerance Expression
Plants	Primary Crop	Bifenthrin	Bifenthrin
	Rotational Crop		
Livestock	Ruminant		

[7] See https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[8] https://www.epa.gov/endocrine-disruption

Table 5.1. Summary of Residues of Concern to be Included in the Risk Assessment and Tolerance Expression.			
Matrix		**Residues Included in Risk Assessment**	**Residues Included in Tolerance Expression**
	Poultry		
Drinking Water		Bifenthrin	N/A[1]

1 N/A – Not Applicable.

5.2 Food Residue Profile

Adequate residue chemistry data have been provided for bifenthrin. Field trials for the proposed new uses on pome fruit, avocado, pomegranate, and *Brassica* leafy vegetables are of an adequate number and geographic representation. Data analyses employed validated analytical methods and are supported by adequate storage stability data. The LOQ reported for the analytical method in crop commodities is 0.05 ppm. The magnitude of the residue data show that when following the proposed patterns of use, detectable residues of bifenthrin are expected in these crops. Decline study data had variable results, but generally showed that residues levels do decline with time. Empirical processing data indicate that residues of bifenthrin concentrate in wet apple pomace (processing factor of 2.5x) following treatment at an exaggerated rate of 5x. In consideration of these data, a separate tolerance is needed for wet apple pomace. Because wet apple pomace can sometimes be fed to cattle, a re-calculation of dietary burden has shown that the tolerances established for bifenthrin on livestock commodities remain appropriate. Recommended tolerances are based on the newly acquired field trial data analyzed for the representative RACs and the tolerance conversions proposed are acceptable. No tolerances have been established for inadvertent or indirect residues of bifenthrin in or on rotational crops and none are needed at this time. No additional residue chemistry data are required for either the established or proposed uses of bifenthrin.

5.3 Water Residue Profile

For conducting the human health risk assessment of bifenthrin, EFED provided Tier I EDWCs to support registration review and the proposed new uses that have been requested by IR-4 (J. Meléndez, D434407, 01/19/2017). EDWCs for bifenthrin were calculated using the aquatic models FQPA Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model for Groundwater (PRZM-GW). EFED determined that the single and seasonal application rates for bifenthrin remain similar to those used in previous assessments, and citrus and lettuce still appear to represent the scenarios with the highest potential exposure (*i.e.*, EDWCs at the limit of solubility of the compound). Based on this information, the current drinking water assessment results do not change from the previous findings reported for bifenthrin.

The EDWCs for bifenthrin were calculated based on a maximum application rate of 0.5 lb ai/A/season. The acute drinking water concentration in surface water is 0.014 µg/L, the limit of solubility for bifenthrin, based on applications of the chemical on lettuce. The cancer/chronic drinking water concentration in surface water is also 0.014 µg/L (based on applications on lettuce, with the highest application rate and PCA). For groundwater, the PRZM-GW generated EDWC is lower than the LOQ for all six scenarios. Based on these assessments, the limit of

solubility of 0.014 µg/L is the EDWC for use in estimating human dietary exposure through drinking water.

A summary of EDWCs determined by EFED for bifenthrin are presented below in Table 5.3.

Table 5.3. Summary of Estimated Surface Water and Groundwater Concentrations for Bifenthrin.

Drinking Water Source (Model Used)	Use (rate modeled)	Maximum EDWC (µg/L)	
Groundwater (PRZM-GW)	Citrus (0.5 lb. ai/A/season)	Acute and Chronic	<LOQ
Surface water (FIRST[1])	Lettuce (0.5 lb. ai/A/season)	Acute	0.014
	Lettuce (0.5 lb. ai/A/season)	Chronic	0.014

1 The FIRST model was used in the previous assessment and it serves as a surrogate for the PWC v.1.52, since the surface water concentrations are not expected to exceed 0.014 µg/L (the solubility of bifenthrin).

5.4 Dietary Risk Assessment

5.4.1 Description of Residue Data Used in Dietary Assessment

Highly refined acute and refined average dietary exposure assessments were conducted for bifenthrin using DEEM-FCID Version 3.18. This model uses 2003-2008 food consumption data from NHANES/WWEIA. A chronic dietary endpoint has not been selected for bifenthrin because repeated exposure does not result in a POD lower than that resulting from acute exposure; therefore, the acute dietary risk assessment is protective of chronic dietary risk. However, since there are residential uses of bifenthrin, a refined chronic dietary exposure assessment was conducted to calculate average (food and drinking water) exposure estimates representing background dietary exposure to support the bifenthrin aggregate risk assessment.

The acute and average assessments were refined using USDA PDP monitoring data, field trial data, PCT data, and empirical processing factors. If monitoring data were not available for a particular commodity, but were available for a similar commodity, the available data were translated to the similar crop and the PCT was adjusted, as appropriate. The acute and average dietary assessments used the solubility of bifenthrin to evaluate exposures via drinking water (0.014 µg/L).

5.4.2 Percent Crop Treated Used in Dietary Assessment

The following maximum Percent Crop Treated (%CT) estimates (Screening Level Usage Analysis (SLUA) 03/24/2016; personal communication with C. Doucoure, 05/23/2017; and Upper-Bound Estimates for New Uses D434404, C. Doucoure, 03/22/2017) for bifenthrin were used in the acute dietary risk assessment: almonds: 35%, apples: 70%, artichoke: 65%, green beans: 55%, blueberries: 5%, broccoli: 20%, Brussel sprouts: 5%, cabbage: 50%, caneberries: 60%, canola: 25%, cantaloupes: 65%, carrots: 10%, cauliflower: 30%, celery: 5%, chicory: 2.5%, citrus (all others): 2.5%, corn: 10%, cotton: 20%, cucumbers: 30%, dry beans/peas: 5%, grapefruit: 2.5%, grapes: 5%, hazelnuts: 5%, honeydews: 75%, lemons: 2.5%, lettuce; 15%, lime: 2.5%, nectarines: 50%, onions: 5%, oranges, 2.5%, peaches: 50%, peanuts: 20%, pears: 2.5%, green peas: 50%, pecans: 15%, peppers (all); 25%, pistachios: 55%, potatoes: 20%,

pumpkins: 45%, soybeans: 5%, spinach: 2.5%, squash: 30%, strawberries: 70%, sweet corn: 50%, tangerines: 2.5%, tomatoes: 30%, walnuts: 35%, watermelons: 30%, wheat: 2.5%.

The following average %CT estimates (Screening Level Usage Analysis (SLUA) 03/24/2016; personal communication with C. Doucoure, 05/23/2017; and Upper-Bound Estimates for New Uses D434404, C. Doucoure, 03/22/2017) for bifenthrin were used to refine the chronic dietary risk assessment for the following crops: almonds: 20%, apples: 60%, artichoke: 20%, green beans: 40%, blueberries: 5%, broccoli: 5%, Brussel sprouts: 2.5%, cabbage: 25%, caneberries: 40%, canola: 10%, cantaloupes: 45%, carrots: 2.5%, cauliflower: 10%, celery: 2.5%, chicory: 1%, citrus (all others): 1%, corn: 5%, cotton: 5%, cucumbers: 10%, dry beans/peas: 2.5%, grapefruit: 1%, grapes: 2.5%, hazelnuts: 2.5%, honeydews: 65%, lemons: 2.5%, lettuce; 15%, lime: 2.5%, nectarines: 40%, onions: 5%, oranges, 1%, peaches: 40%, peanuts: 5%, pears: 2.5%, green peas: 20%, pecans: 5%, peppers (all); 15%, pistachios: 40%, potatoes: 5%, pumpkins: 15%, soybeans: 5%, spinach: 2.5%, squash: 15%, strawberries: 45%, sweet corn: 40%, tangerines: 1%, tomatoes: 15%, walnuts: 20%, watermelons: 15%, wheat: 1%.

A default of 100% CT was used for all livestock and game commodities (based on food and feed contribution), freshwater finfish, and all other registered uses where no maximum/average %CT estimates were given by BEAD. For Food Handling Establishment (FHE) uses, if a tolerance resulting from direct treatment of the crop exists, the residues and %CT resulting from this agricultural use were used in the dietary exposure assessments and assumed to be protective for potential FHE residues and %CT, the latter expected to be significantly lower than residues from direct treatment. However, for foods without tolerances from direct agricultural treatment, half of the limit of detection (LOD) of 0.01 ppm (0.005 ppm) from the warehouse study was used to establish the FHE tolerance (S. Levy, D279905, 08/15/2002). The half LOD value was used in conjunction with the BEAD upper bound %CT estimate of 4.65% for non-fumigant treatments made in FHEs to estimate dietary exposure (D413125, J. Becker, 10/07/2014).

5.4.3 Acute and Average Dietary Risk Assessment & Summary Tables

In order to evaluate the proposed and existing uses, highly-refined acute probabilistic and refined chronic (average) dietary exposure and risk assessments were conducted for three scenarios:

(1) All Existing Uses of Bifenthrin which includes the PDP monitoring data for brassica leafy green subgroup 5B crops grown following a 7-day PHI that can be converted to represent registration of the newly formed subgroup 4-16B crops;
(2) All Existing and Proposed Uses of Bifenthrin.
(3) All Existing and Proposed Uses of Bifenthrin – Alternative Use Pattern. This scenario includes all uses requested by IR-4, except for incorporating the *existing* 7-day PHI for *Brassica* Leafy Greens subgroup 4-16B. Scenario 3 was modeled because Scenario (2) resulted in acute dietary (food and drinking water) risk estimates of concern, and a critical exposure commodity analysis (CEC) found that commodities within group 4-16B were the major contributors to the acute dietary exposure estimates.

All Existing Uses of Bifenthrin
There were no acute dietary (food and drinking water) exposure risk estimates of concern for the U.S. population and all population subgroups for the existing uses of bifenthrin. At the 99.9th

percentile of exposure, the acute dietary risk estimate is 6.2% of the acute population-adjusted dose (aPAD) for the general U.S. population and 51% of the aPAD for all infants (< 1 year old), the most highly exposed population subgroup.

The average (chronic food and drinking water) exposure assessment was conducted solely for the purposes of obtaining a background dietary exposure estimate for use in the aggregate assessment. The population subgroup with the highest average dietary (food and drinking water) exposure estimate is children 1-2 years old (0.000218 mg/kg/day).

Table 5.4.3.1. Summary of the Dietary Exposure and Risk Estimates for the Existing Uses of Bifenthrin.

Population Subgroup	Acute Assessment (99.9th Percentile)			Average (Chronic) Assessment		
	aPAD (mg/kg/day)	Exposure Estimate (mg/kg/day)	% aPAD	cPAD (mg/kg/day)	Exposure Estimate (mg/kg/day)	% cPAD
U.S. Population	0.031	0.001921	6.2	N/A	0.000094	N/A
All infants	**0.01**	**0.005064**	**51**		0.000151	
Children 1-2 yrs*	0.01	0.004008	40		**0.000218**	
Children 3-5 yrs	0.01	0.003377	34		0.000150	
Children 6-12 yrs	0.031	0.001988	6.4		0.000084	
Youth 13-19 yrs	0.031	0.001208	3.9		0.000056	
Adults 20-49 yrs	0.031	0.001332	4.3		0.000095	
Adults 50-99 yrs	0.031	0.001275	4.1		0.000087	
Females 13-49 yrs	0.031	0.001138	3.7		0.000071	

*Most highly exposed population subgroup.

All Existing and Proposed Uses of Bifenthrin

For these analyses, the registered uses of bifenthrin were assessed along with the new permanent tolerances/use patterns requested by IR-4. Because most of the requested new tolerances are existing Section 18 uses or crop group conversions, these uses are already considered in the analyses above for the existing uses of bifenthrin (Table 5.4.3.1). As such, the only new pattern of use proposed by IR-4 is for reducing the existing 7-day PHI for *Brassica* leafy subgroup 4-16B to 1-day. Because this is a new pattern of use and monitoring data do not reflect this use pattern, submitted field trial data, rather than monitoring data, on mustard greens have been used in the dietary assessment for crops in subgroup 4-16B that are representative of the proposed reduced PHI.

For the existing and proposed uses of bifenthrin, the acute dietary (food and drinking water) risk estimates are of concern at the 99.9th percentile of exposure for multiple population subgroups. At the 99.9th percentile of exposure, the acute dietary risk is estimated to be 48% of the aPAD for the general U.S. population and 330% of the aPAD for children 1 to < 2 years old, the most highly exposed population subgroup.

The average (chronic food and drinking water) exposure assessment was conducted solely for the purposes of obtaining background dietary exposure estimates for use in the aggregate assessment. The population subgroup with the highest average dietary (food and drinking water) exposure estimate is children 1-2 years old (0.000327 mg/kg/day).

Table 5.4.3.2. Summary of the Acute Dietary Exposure and Risk Estimates for the Existing and Proposed Uses of Bifenthrin (including 1-day PHI for Brassica leafy greens subgroup 4-16B).						
Population Subgroup	**Acute Assessment (99.9th Percentile)**			**Average (Chronic) Assessment**		
	aPAD (mg/kg/day)	**Exposure Estimate (mg/kg/day)**	**% aPAD**	**cPAD (mg/kg/day)**	**Exposure Estimate (mg/kg/day)**	**% cPAD**
U.S. Population	0.031	0.014859	48	N/A	0.000174	N/A
All infants	0.01	0.024554	250		0.000214	
Children 1-2 yrs*	**0.01**	**0.032770**	**330**		**0.000327**	
Children 3-5 yrs	0.01	0.020207	200		0.000216	
Children 6-12 yrs	0.031	0.017439	56		0.000144	
Youth 13-19 yrs	0.031	0.013777	44		0.000108	
Adults 20-49 yrs	0.031	0.011263	36		0.000157	
Adults 50-99 yrs	0.031	0.016335	53		0.000209	
Females 13-49 yrs	0.031	0.011837	38		0.000131	

*Most highly exposed population subgroup.

All Existing and Proposed Uses of Bifenthrin – Alternative Use Pattern

The existing uses and the additional permanent tolerances requested by IR-4 were also assessed using an alternate pattern of use to determine whether acceptable dietary risk estimates could be derived. For the new *Brassica* leafy subgroup 4-16B crops, field trial data were provided by IR-4 on the representative crop, mustard greens. These data were generated using the maximum proposed seasonal application rate of 0.4 lbs ai/A and a 1-day PHI. As noted above, because this is a new use pattern, monitoring data do not reflect this use pattern, and, therefore, cannot be used in the dietary exposure assessment. Unrefined field trial data were used which resulted in risk estimates of concern (Table 5.4.3.2).

However, there are established tolerances for bifenthrin (3.5 ppm) on *Brassica* leafy greens subgroup 5B crops, representative of a maximum seasonal rate of 0.4 lbs ai/A, and a PHI of 7-days. Because this is an existing use of bifenthrin in crop subgroup 5B, monitoring data are available, which have been used to refine the residue inputs for crops within subgroup 5B in the dietary exposure assessment. However, because mustard greens are the representative crop for both the 5B and 4-16B subgroups, the subgroup 5B pattern of use and supporting data can be extrapolated to the subgroup 4-16B crops to determine whether acceptable dietary risk estimates can be derived based on an alternative PHI of 7-days. Given that the subgroup 5B pattern of use yields lower residues at the 7-day PHI, this alternative for registration of the subgroup 4-16B crops was assessed.

There were no acute dietary (food and drinking water) exposure and risk estimates of concern for the existing and proposed uses of bifenthrin assuming the existing 7-day PHI for *Brassica* leafy greens subgroup 4-16B. At the 99.9th percentile of exposure, the acute dietary risk is estimated to be 6.2% of the aPAD for the general U.S. population, and 51% of the aPAD and for all infants (< 1 year old), the most highly exposed population subgroup.

The average (chronic food and drinking water) exposure assessment was conducted solely for the purposes of obtaining background dietary exposure estimates for use in the aggregate assessment. The population subgroup with the highest average dietary (food and drinking water) exposure estimate is children 1-2 years old (0.000218 mg/kg/day).

Table 5.4.3.2. Summary of the Acute Dietary Exposure and Risk Estimates for the Existing and Proposed Uses of Bifenthrin (including 7-day PHI for Brassica leafy greens subgroup 4-16B).						
Population Subgroup	**Acute Assessment (99.9th Percentile)**			**Average (Chronic) Assessment**		
	aPAD (mg/kg/day)	**Exposure Estimate (mg/kg/day)**	**% aPAD**	**cPAD (mg/kg/day)**	**Exposure Estimate (mg/kg/day)**	**% cPAD**
U.S. Population	0.031	0.001921	6.2	N/A	0.000094	N/A
All infants	**0.01**	**0.005064**	**51**		0.000151	
Children 1-2 yrs*	0.01	0.004008	40		**0.000218**	
Children 3-5 yrs	0.01	0.003377	34		0.000150	
Children 6-12 yrs	0.031	0.001988	6.4		0.000084	
Youth 13-19 yrs	0.031	0.001208	3.9		0.000056	
Adults 20-49 yrs	0.031	0.001332	4.3		0.000095	
Adults 50-99 yrs	0.031	0.001275	4.1		0.000087	
Females 13-49 yrs	0.031	0.001138	3.7		0.000071	

*Most highly exposed population subgroup.

5.4.4 Cancer Dietary Risk Assessment

Bifenthrin is classified as a possible human carcinogen, with quantification of risk using the acute endpoint/POD protective for any potential carcinogenic effects. Therefore, a separate cancer dietary assessment was not performed.

6.0 Residential Exposure/Risk Characterization

There are no proposed residential uses of bifenthrin at this time; however, there are existing residential uses that have been reassessed in this document to reflect updates to HED's 2012 Residential SOPs[9] along with policy changes for body weight assumptions. The following changes have also been incorporated:

- The inhalation scenarios (residential handler) have been reevaluated to incorporate changes to the bifenthrin toxicity database (i.e., incorporating a route-specific inhalation toxicity POD).
- The post-application scenarios have been reevaluated to incorporate chemical-specific TTR and DFR studies.

The revision of residential exposures will impact the human health aggregate risk assessment for bifenthrin.

6.1 Residential Handler Exposure/Risk Estimates

There are registered bifenthrin product labels with residential use sites (e.g., lawns, indoor environments, garden and trees, and pets) that do not require specific clothing (e.g., long sleeve shirt/long pants) and/or PPE, and these labels have been considered in the residential handler assessment for bifenthrin.

[9] Available: http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide

Residential handler exposure assessments were performed for adult homeowners applying bifenthrin RTU products (aerosol, hose-end sprayers, and dog shampoos), mixing/loading/applying liquid concentrates, loading/applying granular formulations, and applying dust formulations. HED has not quantitatively assessed the outdoor residential handler uses in/around home foundations, outdoor impervious surfaces, wood piles/structures, and/or fence posts. The application rates registered for these uses are equal to or lower than those quantitatively assessed for similar use patterns/exposure scenarios; therefore, the current assessment is considered protective of these registered uses sites.

The quantitative exposure/risk assessment developed for residential handlers is based on the scenarios listed in Appendix F, Table F.2.

Residential Handler Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessments. A screening-level approach was used for assessment of residential exposures by evaluation of the maximum application rate for all possible residential handler exposure scenarios of bifenthrin. The registered application rates used for the residential handler quantitative exposure/risk assessment are based on the scenarios listed in Appendix F, Table F.2. The algorithms used to estimate exposure and dose for residential handlers can be found in K. Rickard (D440261 and D441553, 07/19/2017) and in the 2012 Residential SOPs[10].

Unit Exposures and Area Treated or Amount Handled: Unit exposure values and estimates for area treated or amount handled were taken from HED's 2012 Residential SOPs. For ant mound treatments, it was assumed that 5 ant mounds may be treated per day.

Exposure Duration: The toxicological profile of pyrethroids characterizes pyrethroids, including bifenthrin, as being rapid in onset and associated with acute, peak exposures. The single dose and repeat dosing studies show that repeat exposures do not result in lower PODs (i.e., there is no evidence of increasing toxicity with an increased duration of exposure). As such, due to the rapid toxicokinetics and toxicity profile of pyrethroids, the residential assessments are conducted as a series of acute exposures, and the same endpoint/POD is used regardless of duration. Therefore, the acute/single day residential handler assessments are protective of expected short-term exposures.

Residential Handler Non-Cancer Exposure and Risk Estimate Equations

The algorithms used to estimate exposure and dose for residential handlers can be found in the 2012 Residential SOPs.

Combining Exposures/Risk Estimates:

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological effects for these exposure routes were similar. A total aggregated risk index (ARI) was used since the LOCs for dermal exposure (100) and inhalation exposure (30) are different. The target ARI is 1; therefore, ARIs of less than 1 are risk estimates of concern. The aggregate risk index (ARI) was calculated as follows.

[10] Available: http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide

Aggregate Risk Index (ARI) = 1÷ [(Dermal LOC ÷ Dermal MOE) + (Inhalation LOC ÷ Inhalation MOE)]

For residential handlers, exposures from application to turf were not combined with exposures from treating gardens/trees because concurrent use of pesticide products that contain the same active ingredient to treat the same or different pests does not typically occur. Therefore, although the same products allow treatment of gardens/trees and turf, these exposures were not combined for residential handlers.

Summary of Residential Handler Non-Cancer Exposure and Risk Estimates

As shown below in Table 6.1, all of the residential handler combined (dermal + inhalation) ARIs are not of concern.

Table 6.1. Residential Handler Non-Cancer Exposure and Risk Estimates for Bifenthrin.

Formulation	Exposure Scenario	Maximum Application Rate[1]	Area Treated or Amount Handled Daily[2]	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (mg/lb ai)	Dose (mg/kg/day)		MOE[6]		Total
						Dermal[3]	Inhalation[4]	Dermal (LOC = 100)[5]	Inhalation (LOC = 30)[6]	ARI (LOC = 1)[7]
Mixer/Loader/Applicator										
Ready-to-Use	Aerosol can (coarse spray) to indoor environment [Perimeter/ Spot/ Bedbug][8]	0.0005 lb ai/16-oz can	0.5 can	370	3	0.0012	0.0000094	83,000	37,000	500
	Aerosol can with pin stream nozzle to indoor environment [Perimeter/ Spot/ Bedbug][8]	0.00075 lb ai/16-oz can	0.5 can	370	3	0.0017	0.000014	56,000	25,000	330
	RTU Liquid (Manually Pressurized Handwand used as surrogate) to indoor environment [Perimeter/ Spot/ Bedbug]	0.025 lb ai/gal	0.5 gallons	69	1.1	0.0111	0.00017	8,900	2,000	39
	Hose-end Sprayer around gardens/trees	0.00117 lb ai/gallon	11 gallons	6.26	0.034	0.0010	0.0000055	96,000	64,000	660
	Hose-end Sprayer to turf	0.102 lb ai/acre	0.5 acres	6.26	0.034	0.0040	0.000022	24,000	16,000	170
	Shampoo to dogs[8] (Up to 7 lb)	1.6E-05 lb ai/pet	2 pets	2000	0.29	0.00081	0.00000012	120,000	3,000,000	1,200
	Shampoo to dogs[8] (Over 7 to 14 lbs)	3.3E-05 lb ai/pet	2 pets	2000	0.29	0.0016	0.00000024	59,000	1,500,000	580
	Shampoo to dogs[8] (Over 14 to 28 lbs)	6.5E-05 lb ai/pet	2 pets	2000	0.29	0.0033	0.00000047	30,000	740,000	290
	Shampoo to dogs[8] (Over 28 to 42 lbs)	9.8E-05 lb ai/pet	2 pets	2000	0.29	0.0049	0.00000071	20,000	490,000	190
	Shampoo to dogs[8] (Over 42 to 56 lbs)	1.3E-04 lb ai/pet	2 pets	2000	0.29	0.0065	0.00000094	15,000	370,000	150
	Shampoo to dogs[8] (Over 56 to 70 lbs)	1.6E-04 lb ai/pet	2 pets	2000	0.29	0.0081	0.0000012	12,000	300,000	120
	Shampoo to dogs[8] (Over 70 to 84 lbs)	2.0E-04 lb ai/pet	2 pets	2000	0.29	0.0098	0.0000014	9,900	250,000	97

Table 6.1. Residential Handler Non-Cancer Exposure and Risk Estimates for Bifenthrin.

Formulation	Exposure Scenario	Maximum Application Rate[1]	Area Treated or Amount Handled Daily[2]	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (mg/lb ai)	Dose (mg/kg/day)		MOE[6]		Total
						Dermal[3]	Inhalation[4]	Dermal (LOC = 100)[5]	Inhalation (LOC = 30)[6]	ARI (LOC = 1)[7]
	Shampoo to dogs[8] (Over 84 to 98 lbs)	2.3E-04 lb ai/pet	2 pets	2000	0.29	0.011	0.0000017	8,400	210,000	83
	Shampoo to dogs[8] (Over 98 to 112 lbs)	2.6E-04 lb ai/pet	2 pets	2000	0.29	0.013	0.0000019	7,400	190,000	73
	Shampoo to dogs[8] (Over 112 to 126 lbs)	2.9E-04 lb ai/pet	2 pets	2000	0.29	0.015	0.0000021	6,600	160,000	65
	Shampoo to dogs[8] (Over 126 to 140 lbs)	3.3E-04 lb ai/pet	2 pets	2000	0.29	0.016	0.0000024	5,900	150,000	58
Liquid Concentrate	Manually-pressurized handwand (w/ or w/o pin stream nozzle) to indoor environment [Broadcast, Perimeter/Spot/ Bedbug]	0.0041 lb ai/gal	0.5 gallons	69	1.1	0.0018	0.00000028	54,000	12,000	240
	Manually-pressurized handwand around gardens/trees	0.00521 lb ai/gallon	5 gallons	63	0.018	0.021	0.0000059	4,700	60,000	46
	Manually-pressurized handwand to turf	0.00521 lb ai/gallon	5 gallons	63	0.018	0.021	0.0000059	4,700	60,000	46
	Hose-end Sprayer around gardens/trees	0.00521 lb ai/gallon	11 gallons	58	0.0014	0.042	0.000001	2,300	350,000	23
	Hose-end Sprayer to turf	0.196 lb ai/acre	0.5 acres	13.4	0.022	0.016	0.000027	5,900	13,000	52
	Backpack around gardens/trees	0.00521 lb ai/gallon	5 gallons	130	0.14	0.042	0.000046	2,300	7,700	21
	Backpack to turf	0.00521 lb ai/gallon	5 gallons	130	0.14	0.042	0.000046	2,300	7,700	21
	Sprinkler can around gardens/trees	0.00521 lb ai/gallon	5 gallons	58	0.0014	0.019	0.00000046	5,100	770,000	51
	Sprinkler can to turf	5.2 E-5 lb ai/ft^2	1000 ft^2	13.4	0.022	0.0087	0.000014	11,000	24,000	97
	Sprinkler can to turf/ant mounds	0.10 lb ai/mound	5 mounds	13.4	0.022	0.084	0.00014	1,100	2,500	10
Granule	Push-type rotary spreader around gardens/trees	0.0000048 lb ai/ft^2	1200 ft^2	0.81	0.0026	0.000058	0.00000019	1,700,000	1,900,000	13,000
	Push-type rotary spreader to turf	0.21 lb ai/acre	5 acres	0.81	0.0026	0.0011	0.0000034	91,000	100,000	720
	Belly grinder to turf	0.0000048 lb ai/ft^2	1200 ft^2	360	0.039	0.026	0.0000028	3,700	120,000	37
	Spoon around gardens/trees	0.0000048 lb ai/ft^2	1200 ft^2	6.2	0.087	0.00045	0.0000063	220,000	56,000	1,000
	Spoon to turf	0.0000048 lb ai/ft^2	100 ft^2	6.2	0.087	0.000037	0.00000052	2,600,000	670,000	12,000
	Hand dispersal around gardens/trees	0.0000048 lb ai/ft^2	1200 ft^2	160	0.38	0.012	0.000027	8400	13,000	70
	Hand dispersal to turf	0.0000048 lb ai/ft^2	100 ft^2	160	0.38	0.00096	0.0000023	100,000	150,000	840
	Cup around gardens/trees	0.0000048 lb ai/ft^2	1200 ft^2	0.11	0.013	0.0000079	0.00000094	12,000,000	370,000	11,000

Table 6.1. Residential Handler Non-Cancer Exposure and Risk Estimates for Bifenthrin.

Formulation	Exposure Scenario	Maximum Application Rate[1]	Area Treated or Amount Handled Daily[2]	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (mg/lb ai)	Dose (mg/kg/day)		MOE[6]		Total
						Dermal[3]	Inhalation[4]	Dermal (LOC = 100)[5]	Inhalation (LOC = 30)[6]	ARI (LOC = 1)[7]
	Cup to turf	0.0000048 lb ai/ft^2	100 ft^2	0.11	0.013	0.00000066	0.000000078	150,000,000	4,500,000	140,000
	Spoon dispersal to turf/ant mounds	0.00000449 lb ai/mound	5 mounds	6.2	0.087	0.0000017	0.00000024	55,000,000	14,000,000	260,000
Dust	Shaker can to indoor surfaces/voids[10]	0.0000009 lb ai/ft^2	1200 ft^2	4300	18	0.058	0.00024	1,700	1,400	12
	Shaker can to gardens/trees	0.0000005 lb ai/ft^2	1200 ft^2	4300	18	0.032	0.00014	3,000	2,600	22

1 Based on registered labels [see Section 3.3 and Table F.2 (Appendix F)].
2 Based on HED's 2012 Residential SOPs (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide).
3 Dermal Dose = Dermal Unit Exposure (mg/lb ai) × Application Rate (lb ai/acre, gal, or ft^2) × Area Treated or Amount Handled (A/day, gallons/day, or ft^2/day) ÷ Body Weight (80 kg).
4 Inhalation Dose = Inhalation Unit Exposure (mg/lb ai) × Application Rate (lb ai/acre, gal, or ft^2) × Area Treated or Amount Handled (A/day, gallons/day, or ft^2/day) ÷ Body Weight (80 kg).
5 Dermal MOE = Dermal NOAEL (96.3 mg/kg/day) ÷ Dermal Dose (mg/kg/day). LOC = 100.
6 Inhalation MOE = Inhalation Human Equivalent Dose (0.35 mg/kg/day) ÷ Inhalation Dose (mg/kg/day). LOC = 30.
7 ARI = Aggregate Risk Index = 1÷ [(Dermal LOC ÷ Dermal MOE) + (Inhalation LOC ÷ Inhalation MOE)].
8 Application rates for pet shampoo products (lb ai/pet) were calculated assuming registered rate in fl oz, converting to grams (1 fl oz = 29.573529875 grams) and adjusting for % ai in the product. Calculations completed as follows: (% ai/100) × (amount applied (g) ÷ 454 g/lb ai) = lb ai/pet.
9 Ready to Use Aerosol cans are also registered for use in outdoor environments. These exposures are anticipated to be less than those for residential handlers in indoor environments; therefore, the risk estimates are not presented here.
10 Residential handler assessment does not present all applicable indoor application equipment. A shaker can application to interior surfaces/voids provides the highest dermal and inhalation unit exposures and is considered protective of other indoor application equipment/types of applications for bifenthrin (e.g., plunger duster rate = 0.001 lb ai/lb dust, dermal UE = 250 mg/lb ai, Inhalation UE = 1.7 mg/lb ai). MOEs are less for plunger, bulb, and power dusters than for shaker cans for bifenthrin.

6.2 Residential Post-Application Exposure and Risk Estimates

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with bifenthrin. The quantitative exposure/risk assessment for residential post-application exposures is based on the scenarios listed in Table 6.1 which incorporates uses resulting from residential handler applications (Appendix F, Table F.2). In addition, the exposure/risk assessment for residential post-application exposures also incorporates uses resulting from occupational handler application (Appendix F, Table F.4) in residential areas. Post-application exposure has been assessed only for broadcast applications to turf, gardens/trees, indoor environments (carpets and hard floor), and treated pets. Post-application incidental oral and dermal exposures for foundation, perimeter, and spot treatments outdoors, along with post-application inhalation exposure outdoors, is considered negligible.

The lifestages selected for each post-application scenario are based on an analysis provided as an Appendix in the 2012 Residential SOPs[11]. While not the only lifestage potentially exposed for these post-application scenarios, the lifestage that is included in the quantitative assessment is health protective for the exposures and risk estimates for any other potentially exposed lifestage.

Exposure Duration: Residential exposures are expected to be short-, intermediate-, or long-term in duration. The single dose and repeat dosing bifenthrin studies show that repeat

[11] Available: http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide

exposures do not result in lower PODs (i.e., there is no evidence of increasing toxicity with an increased duration of exposure). As such, the residential assessments are conducted as a series of acute exposures, and the same endpoint is used regardless of duration. Therefore, the acute/single day residential post-application assessments are protective of expected short-term exposures.

Ingestion of granules is considered an episodic event and not a routine behavior. Because HED does not believe that this would occur on a regular basis, our concern for human health is related to acute poisoning rather than short-term residue exposure. Therefore, an acute dietary POD is used to estimate exposure and risk resulting from episodic ingestion of granules.

Exposure Assessment Assumptions: A series of assumptions and exposure factors served as the basis for completing the residential post-application risk assessment. A screening-level approach was used for assessment of residential exposures by evaluation of the maximum application rate for the representative residential post-application exposure scenarios of bifenthrin. The maximum rates for all registered uses of bifenthrin are summarized in Appendix F. The assumptions, factors, and algorithms used to estimate residential post-application exposures and doses are detailed in the 2012 Residential SOPs[11]. In addition to the Residential SOPs, a number of pyrethroid-specific assumptions and inputs were selected for use in the residential post-application scenarios. These inputs are generic to pyrethroids, but diverge from those recommended in the Residential SOPs. In conjunction with the pyrethroid-specific inputs, bifenthrin-specific DFR and TTR data using liquid formulations were also used. Additional TTR/DFR data using a granular formulation could be submitted to refine the residential and occupational post-application assessments in the future. The assumptions used for the post-application residential assessment are summarized in Appendix G and in K. Rickard (D440261 and D441553, 07/19/2017).

Combining Exposure and Risk Estimates:
Dermal and incidental oral risk estimates were combined in this assessment since the toxicological effects for evaluating these exposure routes were similar. The incidental oral scenarios (i.e., hand-to-mouth and object-to-mouth) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Combining these scenarios with the dermal exposure scenario would be overly-conservative because of the conservative nature of each individual assessment. Therefore, the post-application exposure scenarios that were combined for children 1 to < 2 years old are the dermal and hand-to-mouth scenarios. This combination should be considered a protective estimate of children's exposure.

Summary of Residential Post-Application Non-Cancer Exposure and Risk Estimates
The majority of residential post-application exposures did not result in risk estimates of concern; however, the following residential post-application scenarios resulted in risk estimates of concern:

Children (1 to < 2 years old):

- High contact activities following liquid application to lawns/turf (dermal MOE = 21, LOC = 300)
- Hand-to-mouth exposures following liquid application to lawns/turf (MOE = 32, LOC =

300)

- Combined dermal and hand-to-mouth exposures following liquid application to lawns/turf (MOE = 13, LOC = 300)
- High contact activities following granular application to lawns/turf (dermal MOE =110, LOC = 300)
- Combined dermal and hand-to-mouth exposures following solid applications to lawns/turf (MOE = 85, LOC = 300)
- Episodic granular ingestion following application to lawns/turf (acute/episodic ingestion MOE = 57, LOC = 300)

Adults:

- High contact activities following liquid application to lawns/turf (dermal MOE = 41, LOC = 100)

Table 6.2. Residential Post-Application Non-Cancer Exposure and Risk Estimates for Bifenthrin.

Lifestage	Post-Application Scenario		Deposited Residue (µg/cm²) or Application rate (lb ai/A)[1]	Dose (mg/kg/day)[2]	MOEs[3]	Combined Routes (X indicates included in Combined MOE)	Combined MOE (LOC = 300 for Children 1 to < 2, LOC = 100 for adults, children 6 to < 11 years old, and children 11 to 16 years old)
Indoor Environments							
Indoor Spray - Perimeter/Spot/Bedbug (coarse)							
Adult	Carpet	Dermal	Deposited residue (ug/cm²) = 2.6 for carpet/hard surfaces, 2.53 for mattress	0.035	2,700		
	Hard Surface	Dermal		0.018	5,400		
	Mattress	Dermal		0.011	9,100		
Child 1 to <2 years	Carpet	Dermal		0.034	2,800	X	440
		Hand to Mouth		0.0051	610	X	
		Object to Mouth		0.00068	4,600		
	Mattress	Dermal		0.024	4,000	X	
	Hard Surfaces	Dermal		0.034	2,800	X	700
		Hand to Mouth		0.0026	1,200	X	
		Object to Mouth		0.00068	4,600		
	Mattress	Dermal		0.024	4,000	X	
Indoor Spray - Perimeter/Spot/Bedbug (Pin Stream)							
Adult	Carpet	Dermal	Deposited residue (ug/cm²) = 1.5 for carpet/hard surfaces	0.02	4,700		
	Hard Surface	Dermal		0.01	9,400		
Child 1 to <2 years	Carpet	Dermal		0.02	4,900	X	870
		Hand to Mouth		0.0029	1,100	X	
		Object to Mouth		0.00039	7,900		
	Hard Surface	Dermal		0.02	4,900	X	1500
		Hand to Mouth		0.0015	2,100	X	
		Object to Mouth		0.00039	7,900		

Table 6.2. Residential Post-Application Non-Cancer Exposure and Risk Estimates for Bifenthrin.

Lifestage	Post-Application Scenario		Deposited Residue (µg/cm²) or Application rate (lb ai/A)[1]	Dose (mg/kg/day)[2]	MOEs[3]	Combined Routes (X indicates included in Combined MOE)	Combined MOE (LOC = 300 for Children 1 to < 2, LOC = 100 for adults, children 6 to < 11 years old, and children 11 to 16 years old)
Indoor Spray - Perimeter/Spot/Bedbug (Pin Stream)							
Adult	Carpet	Dermal	Deposited residue (ug/cm²) = 0.4	0.0054	18,000		
	Hard Surface	Dermal		0.0027	35,000		
Child 1 to <2 years	Carpet	Dermal		0.0052	18,000	X	3,200
		Hand to Mouth		0.00079	3,900	X	
		Object to Mouth		0.00010	30,000		
	Hard Surfaces	Dermal		0.0052	18,000	X	5,500
		Hand to Mouth		0.00039	7,900	X	
		Object to Mouth		0.00010	30,000		
Lawns and Turf[5]							
Liquid Formulations							
Adult	High Contact Lawn Activities	Dermal	2.3 lb ai/A	2.37	**41**		
	Mowing Turf		2.3 lb ai/A	0.048	2,000		
	Golfing		0.2 lb ai/A	0.016	6,000		
Child 1 to <2 years	High Contact Lawn Activities	Dermal	2.3 lb ai/A	4.69	**21**	X	**13**
	Lawns/Turf	Hand to Mouth	2.3 lb ai/A	0.096	**32**	X	
		Object to Mouth	2.3 lb ai/A	0.0029	1,100		
		Soil ingestion	2.3 lb ai/A	0.000078	40,000		
Child 6 to <11 years	Golfing	Dermal	0.2 lb ai/A	0.022	4,400		
Child 11 to <16 years	Mowing Turf	Dermal	2.3 lb ai/A	0.055	1,700		
	Golfing		0.2 lb ai/A	0.019	5,100		
Solid Formulations							
Adult	High Contact Lawn Activities	Dermal	0.4 lb ai/A	0.46	210		
	Mowing Turf		0.4 lb ai/A	0.0083	11,000		
	Golfing		0.4 lb ai/A	0.032	3,000		
Children 1 to < 2	High Contact Lawn Activities	Dermal	0.4 lb ai/A	0.90	**110**	X	**85**
		Hand to Mouth	0.4 lb ai/A	0.0083	370	X	
		Object to Mouth	0.4 lb ai/A	0.00051	6,100		
		Soil ingestion	0.4 lb ai/A	0.000014	230,000		

Table 6.2. Residential Post-Application Non-Cancer Exposure and Risk Estimates for Bifenthrin.							
Lifestage	**Post-Application Scenario**		**Deposited Residue (µg/cm²) or Application rate (lb ai/A)[1]**	**Dose (mg/kg/day)[2]**	**MOEs[3]**	**Combined Routes (X indicates included in Combined MOE)**	**Combined MOE (LOC = 300 for Children 1 to < 2, LOC = 100 for adults, children 6 to < 11 years old, and children 11 to 16 years old)**
		Episodic Granule ingestion	0.4 lb ai/A	0.055	**57**		
Child 6 to <11 years	Golfing	Dermal	0.4 lb ai/A	0.044	2,200		
Child 11 to <16 years	Mowing	Dermal	0.4 lb ai/A	0.0096	10,000		
	Golfing	Dermal	0.4 lb ai/A	0.038	2,600		
Garden and Trees							
Liquid Formulations							
Adult	Gardens	Dermal	0.23 lb ai/A	0.143	670		
	Trees		0.23 lb ai/A	0.013	7,300		
	Indoor plants		0.23 lb ai/A	0.0017	57,000		
Child 6 to <11 years	Gardens		0.23 lb ai/A	0.098	990		
	Trees		0.23 lb ai/A	0.009	11,000		
	Indoor plants		0.23 lb ai/A	0.0012	83,000		
Solid Formulations							
Adult	Gardens	Dermal	0.21 lb ai/A	0.130	740		
	Trees		0.21 lb ai/A	0.012	8,000		
	Indoor Plants		0.21 lb ai/A	0.0016	62,000		
Child 6 to <11 years	Gardens		0.21 lb ai/A	0.089	1,100		
	Trees		0.21 lb ai/A	0.008	12,000		
	Indoor Plants		0.21 lb ai/A	0.0011	91,000		
Treated Pets (Dogs Treated with Shampoos)							
Adult	Dogs (Up to 7 lb)	Dermal	7.4 mg ai	0.0032	30,000		
	Dogs (Over 7 to 14 lbs)	Dermal	14.8 mg ai	0.0064	15,000		
	Dogs (Over 14 to 28 lbs)	Dermal	29.6 mg ai	0.0081	12,000		
	Dogs (Over 28 to 42 lbs)	Dermal	44.4 mg ai	0.0078	12,000		
	Dogs (Over 42 to 56 lbs)	Dermal	59.1 mg ai	0.0079	12,000		
	Dogs (Over 56 to 70 lbs)	Dermal	73.9 mg ai	0.0082	12,000		
	Dogs (Over 70 to 84 lbs)	Dermal	88.7 mg ai	0.0086	11,000		
	Dogs (Over 84 to 98 lbs)	Dermal	103.5 mg ai	0.0089	11,000		
	Dogs (Over 98 to 112 lbs)	Dermal	118.3 mg ai	0.0092	11,000		
	Dogs (Over 112 to 126 lbs)	Dermal	133.1 mg ai	0.0095	10,000		

Table 6.2. Residential Post-Application Non-Cancer Exposure and Risk Estimates for Bifenthrin.							
Lifestage	**Post-Application Scenario**		**Deposited Residue (µg/cm²) or Application rate (lb ai/A)[1]**	**Dose (mg/kg/day)[2]**	**MOEs[3]**	**Combined Routes (X indicates included in Combined MOE)**	**Combined MOE (LOC = 300 for Children 1 to < 2, LOC = 100 for adults, children 6 to < 11 years old, and children 11 to 16 years old)**
	Dogs (Over 126 to 140 lbs)	Dermal	147.9 mg ai	0.0097	9,900		
Child (1 < 2 yrs)	Dogs (Up to 7 lb)	Dermal	7.4 mg ai	0.0011	87,000		8,700
	Dogs (Over 7 to 14 lbs)	Dermal	14.8 mg ai	0.0022	43,000		
	Dogs (Over 14 to 28 lbs)	Dermal	29.6 mg ai	0.0028	34,000		
	Dogs (Over 28 to 42 lbs)	Dermal	44.4 mg ai	0.0027	35,000		
	Dogs (Over 42 to 56 lbs)	Dermal	59.1 mg ai	0.0028	35,000		
	Dogs (Over 56 to 70 lbs)	Dermal	73.9 mg ai	0.0029	33,000		
	Dogs (Over 70 to 84 lbs)	Dermal	88.7 mg ai	0.0030	32,000		
	Dogs (Over 84 to 98 lbs)	Dermal	103.5 mg ai	0.0031	31,000		
	Dogs (Over 98 to 112 lbs)	Dermal	118.3 mg ai	0.0032	30,000		
	Dogs (Over 112 to 126 lbs)	Dermal	133.1 mg ai	0.0033	29,000		
	Dogs (Over 126 to 140 lbs)	Dermal	147.9 mg ai	0.0034	28,000	X	
	Dogs (Up to 7 lb)	Hand to Mouth	7.4 mg ai	0.000081	38,000		
	Dogs (Over 7 to 14 lbs)	Hand to Mouth	14.8 mg ai	0.00016	19,000		
	Dogs (Over 14 to 28 lbs)	Hand to Mouth	29.6 mg ai	0.00021	15,000		
	Dogs (Over 28 to 42 lbs)	Hand to Mouth	44.4 mg ai	0.00020	16,000		
	Dogs (Over 42 to 56 lbs)	Hand to Mouth	59.1 mg ai	0.00020	15,000		
	Dogs (Over 56 to 70 lbs)	Hand to Mouth	73.9 mg ai	0.00021	15,000		
	Dogs (Over 70 to 84 lbs)	Hand to Mouth	88.7 mg ai	0.00022	14,000		
	Dogs (Over 84 to 98 lbs)	Hand to Mouth	103.5 mg ai	0.00023	14,000		
	Dogs (Over 98 to 112 lbs)	Hand to Mouth	118.3 mg ai	0.00023	13,000		
	Dogs (Over 112 to 126 lbs)	Hand to Mouth	133.1 mg ai	0.00024	13,000		
	Dogs (Over 126 to 140 lbs)	Hand to Mouth	147.9 mg ai	0.00025	13,000	X	

1 Based on registered bifenthrin uses (See Section 3.3 and Appendix F).
2 Dose (mg/kg/day) algorithms provided in 2012 Residential SOPs (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide).
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day), where dermal POD = 96.3 mg/kg/day and incidental oral/acute dietary (episodic granular ingestion) POD = 3.1 mg/kg/day.
4 Combined MOE = 1÷ [1/(Dermal MOE) + (1/Incidental Oral MOE)].
5 For lawns/turf, application rates derived from EPA Reg. No. 279-3152 (Liquid) and EPA Reg. No. 279-9547 (Granular).

6.3 Residential Risk Estimates for Use in Aggregate Assessment

As identified in Section 6.2, some exposure scenarios on treated turf resulted in post-application risk estimates of concern for adults and children. These exposure scenarios have not been considered for the purpose of performing an aggregate assessment since additional exposure from food and water would only increase the risk estimates.

Of the remaining residential exposure scenarios, only the most conservative, or worst case, residential adult and child scenarios have been selected to be included in the aggregate risk assessment. A summary of the residential exposures and risk estimates recommended for the aggregate assessment is provided in Table 6.3.

Ingestion of granules is considered an episodic event and not a routine behavior. Because HED does not believe that this would occur on a regular basis, our concern for human health is related to acute poisoning rather than short-term residue exposure. Therefore, an acute dietary dose is used to estimate exposure and risk resulting from episodic ingestion of granules. For these same reasons, the episodic ingestion scenario is not recommended for inclusion in the aggregate assessment.

Table 6.3. Recommended Residential Exposures for the Bifenthrin Aggregate Assessment.

Lifestage	Exposure Scenario	Dose (mg/kg/day)[1]				MOE[2]			
		Dermal	Inhalation	Oral	Total	Dermal	Inhalation	Oral	Total
Adults	Post-Application Exposure from High Contact Activities on Turf Treated with Granular Formulation	0.458	N/A	N/A	0.458	210	N/A	N/A	210
Children 1 to < 2 years old	Post-Application Exposure from Activities on Treated Carpet	0.034		0.0051	0.0634	2,800		610	440
	Post-Application Exposure from Treated Mattress	0.024		NA		4,000		NA	
Children 6 to < 11 years old	Post-Application Exposure to Treated Gardens	0.098		N/A	0.0977	990		N/A	990
Children 11 to 16 years old	Mowing Turf Treated with Liquid Formulations	0.056			0.0554	1,700			1,700

1 Dose = the highest dose for each applicable lifestage of all residential scenarios assessed. Total = dermal + inhalation + incidental oral (where applicable).
2 MOE = the MOEs associated with the highest residential doses. Total/combined MOE = 1÷ [1/(Dermal MOE) + (1/Incidental Oral MOE)].

7.0 Aggregate Exposure/Risk Characterization

In accordance with the FQPA, HED must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate

assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure. A chronic aggregate assessment was not conducted since single dose and repeat dosing bifenthrin studies show that repeat exposures do not result in lower PODs (i.e., there is no evidence of increasing toxicity with an increased duration of exposure). Therefore, only acute and short-term aggregate risk assessments need to be conducted for bifenthrin, and these are protective of scenarios in which exposure occurs for multiple days.

7.1 Acute Aggregate Risk

The acute aggregate risk assessment combines exposures to bifenthrin in food and drinking water only. In order to evaluate the proposed and existing uses, highly-refined acute probabilistic dietary exposure and risk assessments were conducted for three Scenarios. Therefore, these scenarios are also applicable to the aggregate assessment.

All Existing Uses of Bifenthrin
The acute aggregate risk assessment combines exposures to bifenthrin in food and drinking water only. For the existing uses of bifenthrin only, the acute dietary exposure and risk estimates do not exceed HED's level of concern (less than 100% of the aPAD). At the 99.9th exposure percentile of exposure, the acute dietary risk estimate is 6.2% of the aPAD for the general U.S. population and 51% of the aPAD for all infants (< 1 year old), the most highly exposed population subgroup (see Section 5.4.3).

All Existing and Proposed Uses of Bifenthrin
For the existing and proposed uses of bifenthrin (including the 1-day PHI for *Brassica* leafy greens subgroup 4-16B), the acute dietary (food and drinking water) risk estimates are <u>of concern</u> at the 99.9th percentile of exposure for multiple population subgroups. At the 99.9th percentile of exposure, the acute dietary risk estimate is estimated to be 48% of the aPAD for the general U.S. population and 330% of the aPAD for children 1 to < 2 years old, the most highly exposed population subgroup (see Section 5.4.3).

All Existing and Proposed Uses of Bifenthrin - Alternative Use Pattern
There were no acute dietary (food and drinking water) exposure and risk estimates of concern for the existing and proposed uses of bifenthrin assuming the existing 7-day PHI for *Brassica* leafy greens subgroup 4-16B. At the 99.9th percentile of exposure, the acute dietary risk estimate is estimated to be 6.2% of the aPAD for the general U.S. population, and 51% of the aPAD and for all infants (< 1 year old), the most highly exposed population subgroup (see Section 5.4.3).

7.2 Short-Term Aggregate Risk

Short-term aggregate risk assessments are necessary for both adults and children since there is the potential for both short-term handler exposure and short-term post-application exposure from the residential uses of bifenthrin. For the short-term aggregate risk assessment, potential residential post-application exposures (Table 6.3) were combined with average food and drinking water exposures (Section 5.4.3).

For the adult aggregate assessment, dermal post-application exposure following high contact activities on turf treated with granular formulations resulted in the highest short-term exposures; therefore, this exposure estimate was aggregated with food and drinking water exposures.

For the children 1 to < 2 year old aggregate assessment, indoor treatments for bedbugs resulted in the highest combined exposure estimates. If a product registered for use to treat bedbug is labeled for use as an indoor crack and crevice/perimeter/spot application, and mattress application, the potential exists for both of these exposures to reasonably occur within a day's time. A child may contact the treated floor and sleep in a treated bed within the course of a day. Therefore, dermal and hand-to-mouth post-application exposure following contact with carpets treated for bedbugs were combined with dermal exposures from contacting mattresses treated for bedbugs. These combined (dermal and hand-to-mouth) exposure estimates were aggregated with food and drinking water exposures.

For the children 6 to < 11 years old aggregate assessment, the highest residential exposures resulted from post-application dermal exposures from contacting treated gardens. For children 11 to < 16 years old, the highest residential exposures resulted from mowing turf treated with liquid formulations. Therefore, aggregate (food, drinking water, and residential) exposure assessment were conducted for these residential exposure scenarios and lifestages.

A 1/MOE[12] approach was used for the short-term aggregate assessments since the oral and dermal PODs are different, but the LOCs are the same within each population subgroup (LOC for adults and children > 6 years = 100, LOC for children < 6 years = 300).

Because acute dietary risk estimates of concern were identified for the proposed uses of bifenthrin, three dietary exposure assessment scenarios were conducted to generate average (chronic) dietary exposure and risk assessments to inform risk management decisions for the proposed and existing uses of bifenthrin. Average food and drinking water estimates were combined with potential residential exposures to generate an aggregate exposure and risk assessment.

All Existing Uses of Bifenthrin

The short-term aggregate (food, drinking water, residential exposures) assessment for adults resulted in an MOE of 210 (LOC = 100). The short-term aggregate (food, drinking water, and residential exposure) assessment for children 1 to <2 years old resulted in an MOE of 430 (LOC = 300). The short-term aggregate (food, drinking water, residential exposures) assessment for children 6 to < 11 years old and children 11 to 16 years old resulted in MOEs of 960 and 1,700, respectively.

Table 7.2.1. Short-Term Aggregate Risk Assessment for Existing Uses of Bifenthrin.

Population	LOC for Aggregate Risk[1]	Dietary Exposure		Dermal Residential Exposure		Oral Residential Exposure		Aggregate MOE (food, water, and residential)[5]
		mg/kg/day	MOE[2]	mg/kg/day[3]	MOE	mg/kg/day[4]	MOE	
Adults	100	0.000095	33,000	0.458	210	N/A	N/A	210

[12] Total/combined MOE = 1÷ [1/(Dermal MOE) + (1/Incidental Oral MOE)].

Table 7.2.1. Short-Term Aggregate Risk Assessment for Existing Uses of Bifenthrin.								
Population	LOC for Aggregate Risk[1]	Dietary Exposure		Dermal Residential Exposure		Oral Residential Exposure		Aggregate MOE (food, water, and residential)[5]
		mg/kg/day	MOE[2]	mg/kg/day[3]	MOE	mg/kg/day[4]	MOE	
Children 1 to < 2 years old	300	0.000218	14,000	0.0583	1,700	0.0051	610	430
Children 6 to < 11 years old	100	0.000084	37,000	0.0977	990	N/A	N/A	960
Children 11 to 16 years old	100	0.000056	55,000	0.0554	1,700	N/A	N/A	1,700

1 Adult and children > 6 years old LOC = 100 (10X for interspecies, 10X for intraspecies, 1X FQPA SF). Children < 6 years old LOC = 300 (10X interspecies, 10X intraspecies, 3X FQPA).
2 MOE dietary = [($BMDL_{1SD}$= 3.1 mg/kg)/(chronic dietary exposure)]. Adults = average dietary exposures for Adults (20-49 years old).
3 MOE dermal = [($BMDL_{10}$= 96.3 mg/kg)/(dermal residential exposure)]. See Table 6.3.
4 MOE oral = [($BMDL_{1SD}$= 3.1 mg/kg)/(hand-to-mouth residential exposure)]. See Table 6.3.
5 MOE Aggregate = 1/[(1/MOE dietary) + (1/MOE dermal) + (1/MOE oral)].

All Existing and Proposed Uses of Bifenthrin

The short-term aggregate (food, drinking water, residential exposures) assessment for adults resulted in an MOE of 210 (LOC = 100). The short-term aggregate (food, drinking water, and residential exposure) assessment for children 1 to <2 years old resulted in an MOE of 420 (LOC = 300). The short-term aggregate (food, drinking water, residential exposures) assessment for children 6 to < 11 years old and children 11 to 16 years old resulted in MOEs of 940 and 1,600, respectively.

Table 7.2.2. Short-Term Aggregate Risk Assessment for Existing Uses and Proposed Uses of Bifenthrin (Including 1-day PHI for *Brassica* Leafy Greens Subgroup 4-16B).								
Population	LOC for Aggregate Risk[1]	Dietary Exposure		Dermal Residential Exposure		Oral Residential Exposure		Aggregate MOE (food, water, and residential)[5]
		mg/kg/day	MOE[2]	mg/kg/day[3]	MOE	mg/kg/day[4]	MOE	
Adults	100	0.000209	15,000	0.458	210	N/A	N/A	210
Children 1 to < 2 years old	300	0.000327	9,500	0.0583	1,700	0.0051	610	420
Children 6 to < 11 years old	100	0.000144	22,000	0.0977	990	N/A	N/A	940
Children 11 to 16 years old	100	0.000108	28,000	0.0554	1,700	N/A	N/A	1,600

1 Adult and children > 6 years old LOC = 100 (10X for interspecies, 10X for intraspecies, 1X FQPA SF). Children < 6 years old LOC = 300 (10X interspecies, 10X intraspecies, 3X FQPA).
2 MOE dietary = [($BMDL_{1SD}$= 3.1 mg/kg)/(chronic dietary exposure)]. Adults = average dietary exposures for Adults (50-99 years old).
3 MOE dermal = [($BMDL_{10}$= 96.3 mg/kg)/(dermal residential exposure)]. See Table 6.3.
4 MOE oral = [($BMDL_{1SD}$= 3.1 mg/kg)/(hand-to-mouth residential exposure)]. See Table 6.3.
5 MOE Aggregate = 1/[(1/MOE dietary) + (1/MOE dermal) + (1/MOE oral)].

All Existing and Proposed Uses – Alternative Use Pattern

The short-term aggregate (food, drinking water, residential exposures) assessment for adults resulted in an MOE of 210 (LOC = 100). The short-term aggregate (food, drinking water, and residential exposure) assessment for children 1 to <2 years old resulted in an MOE of 430 (LOC = 300). The short-term aggregate (food, drinking water, residential exposures) assessment for children 6 to < 11 years old and children 11 to 16 years old resulted in MOEs of 960 and 1,700, respectively.

Table 7.2.3. Short-Term Aggregate Risk Assessment for Existing Uses and Proposed Uses of Bifenthrin (Except Assuming Existing 7-day PHI for *Brassica* Leafy Greens Subgroup 4-16B, Instead of Proposed 1-Day PHI).

Population	LOC for Aggregate Risk[1]	Dietary Exposure		Dermal Residential Exposure		Oral Residential Exposure		Aggregate MOE (food, water, and residential)[5]
		mg/kg/day	MOE[2]	mg/kg/day[3]	MOE	mg/kg/day[4]	MOE	
Adults	100	0.000095	33,000	0.458	210	N/A	N/A	210
Children 1 to < 2 years old	300	0.000218	14,000	0.0583	1,700	0.0051	610	430
Children 6 to < 11 years old	100	0.000084	37,000	0.0977	990	N/A	N/A	960
Children 11 to 16 years old	100	0.000056	55,000	0.0554	1,700	N/A	N/A	1,700

1 Adult and children > 6 years old LOC = 100 (10X for interspecies, 10X for intraspecies, 1X FQPA SF). Children < 6 years old LOC = 300 (10X interspecies, 10X intraspecies, 3X FQPA).
2 MOE dietary = [($BMDL_{1SD}$= 3.1 mg/kg)/(chronic dietary exposure)]. Adults = average dietary exposures for Adults (20-49 years old).
3 MOE dermal = [($BMDL_{10}$= 96.3 mg/kg)/(dermal residential exposure)]. See Table 6.3.
4 MOE oral = [($BMDL_{1SD}$= 3.1 mg/kg)/(hand-to-mouth residential exposure)]. See Table 6.3.
5 MOE Aggregate = 1/[(1/MOE dietary) + (1/MOE dermal) + (1/MOE oral)].

7.3 Cancer Aggregate Risk

Bifenthrin is classified as a possible human carcinogen, with quantification of risk using the acute endpoint/POD protective for any potential carcinogenic effects. Therefore, a separate cancer dietary assessment was not performed.

8.0 Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Estimates

Volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html). The Agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219).

During Registration Review, the Agency will utilize this analysis to determine if data (i.e., flux studies, additional route-specific inhalation toxicological studies) or further analysis is needed for bifenthrin.

For some scenarios, such as pet treatments, a quantitative residential post-application inhalation exposure assessment was not performed as inhalation exposure is expected to be negligible from these types of applications. However, an inhalation exposure assessment was performed for occupational handlers (i.e., groomers, treaters, etc.) and this exposure scenario should be considered protective of any potential low-level post-application inhalation exposure that could result from these types of applications.

9.0 Non-Occupational Spray Drift Exposure and Risk Estimates

Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (*e.g.*, children playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues can be calculated using drift modeling onto 50 feet wide lawns coupled with methods employed for residential risk assessments for turf products.

The approach to be used for quantitatively incorporating spray drift into risk assessment is based on a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them.[13] Direct exposures would include inhalation of the spray plume or being sprayed directly. Rather, the exposures addressed here are thought to occur indirectly through contact with impacted areas, such as residential lawns, when compliant applications are conducted. Given this premise, exposures for children (1 to 2 years old) and adults who have contact with turf where residues are assumed to have deposited via spray drift thus resulting in an indirect exposure are the focus of this analysis analogous to how exposures to turf products are considered in risk assessment.

In order to evaluate the drift potential and associated risks, an approach based on drift modeling coupled with techniques used to evaluate residential uses of pesticides was utilized. Essentially, a residential turf assessment based on exposure to deposited residues has been completed to address drift from the agricultural applications of bifenthrin. In the spray drift scenario, the deposited residue value was determined based on the amount of spray drift that may occur at varying distances from the edge of the treated field using the AgDrift (v2.1.1) model and the *Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift Policy*. Once the deposited residue values were determined, the remainder of the spray drift assessment was based on the algorithms and input values specified in the recently revised (2012) *Standard Operating Procedures for Residential Risk Assessment (SOPs)*.
A screening approach was developed based on the use of the AgDrift model in situations where specific label guidance that defines application parameters is not available.[14] AgDrift is appropriate for use only when applications are made by aircraft, airblast orchard sprayers, and groundboom sprayers. When AgDrift was developed, a series of screening values (i.e., the Tier 1 option) were incorporated into the model and represent each equipment type and use under varied conditions. The screening options specifically recommended in this methodology were selected because they are plausible and represent a reasonable upper bound level of drift for common application methods in agriculture. These screening options are consistent with how spray drift is considered in a number of ecological risk assessments and in the process used to develop drinking water concentrations used for risk assessment. In all cases, each scenario is to be evaluated unless it is not plausible based on the anticipated use pattern (e.g., herbicides are not typically applied to tree canopies) or specific label prohibitions (e.g., aerial applications are not allowed).

[13] This approach is consistent with the requirements of the EPA's Worker Protection Standard.
[14] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#AgDrift

Several bifenthrin products have existing labels for use on turf, thus it was considered whether the risk assessment for that use may be considered protective of any type of exposure that would be associated with spray drift. It should be noted that the registered residential uses on turf result in exposure greater than potential exposure from spray drift. If the maximum application rate on crops adjusted by the amount of drift expected is less than or equal to existing turf application rates, the existing turf assessment is considered protective of spray drift exposure. The currently registered maximum single application rate of bifenthrin expected to result in drift is 0.4 lb ai/A. The highest degree of spray drift noted for any application method immediately adjacent to a treated field (Tier 1 output from the aerial application using fine to medium spray quality) results in a deposition fraction of 0.26 of the application rate. Although the registered maximum application rate to a crop/target site expected to result in spray drift (0.4 lb ai/A)[15] multiplied by the adjustment factor for drift of 0.26 is less than the maximum direct spray residential turf application rate of 2.3 lb ai/A (liquid)[16], some post-application risk estimates for the direct spray turf use are of concern for adults and children. Therefore, a quantitative spray drift assessment has been conducted for the registered and proposed uses of bifenthrin. Section 9.1 provides the screening level drift related risk estimates. In many cases, risks are of concern when the screening level estimates for spray drift are used as the basis for the analysis. In order to account for this issue and to provide additional risk management options additional spray drift deposition fractions were also considered. These drift estimates represent plausible options for pesticide labels.

9.1 Combined Risk Estimates From Lawn Deposition Adjacent to Applications

The spray drift risk estimates are based on an estimated deposited residue concentration as a result of the screening level agricultural application scenarios. Bifenthrin is used on various agricultural field and tree crops, and non-agricultural areas (sod farms, etc) and can be applied via airblast, groundboom, and aerial equipment. The recommended drift scenario screening level options are listed below:

- **Groundboom applications** are based on the AgDrift option for high boom height and using very fine to fine spray type using the 90th percentile results.
- **Orchard airblast applications** are based on the AgDrift option for Sparse (Young/Dormant) tree canopies.
- **Aerial applications** are based on the use of AgDrift Tier 1 aerial option for a fine to medium spray type and a series of other parameters which will be described in more detail below (e.g., wind vector assumed to be 10 mph in a downwind direction for entire application/drift event).[17]

In addition to the screening level spray drift scenarios described above, additional results are provided in Appendix D (spreadsheets) of D440261 and D441553 (K. Rickard, 07/19/2017)

[15] The spray drift assessment did not consider applications to tree trunks for trees grown for non-commercial purposes (0.6 lb ai/A) as a directed spray would be completed with a handgun sprayer. Spray drift is not expected with handheld equipment.
[16] 0.4 lb ai/A x 0.26 ≤ 2.3 lb ai/A
[17] AgDrift allows for consideration of even finer spray patterns characterized as very fine to fine. However, this spray pattern was not selected as the common screening basis since it is used less commonly in agriculture.

which represent viable drift reduction technologies (DRTs) that represent potential risk management options. In particular, different spray qualities have been considered as well as the impact of other application conditions (e.g., boom height, use of a helicopter instead of fixed wing aircraft, crop canopy conditions).

The applicable LOC for adult dermal exposures is an MOE of 100. Dermal and incidental oral risk estimates were combined for children 1 to < 2 years old because the toxicity endpoint for each route of exposure is based on neurotoxicity; therefore, the total applicable LOC is 300. Exposures were considered for 50 feet wide lawns where the nearest side of the property was directly adjoining the treated field (at field edge) and at varied distances up to 300 feet downwind of a treated field.

There were no dermal risk estimates of concern at the field edge for adults following applications to all registered crops at the maximum registered application rates and assuming screening-level droplet sizes and boom heights as noted above (MOEs > 100). The dermal MOEs for adults range from 910 to 16,000 at the field edge (LOC = 100). However, for children 1 to < 2 years old, some combined dermal and incidental oral MOEs were of concern (MOE < 300) at the field edge from aerial applications to crops with application rates of 0.40 lb ai/A (tobacco). At the field edge, combined dermal and incidental oral MOEs ranged from 280 to 4,900 (LOC = 300). Aerial sprays to tobacco required distances of 10 feet from the field edge to result in risk estimates not of concern (MOE = 350).

The impact of changing nozzle types resulting in coarser sprays, which drift less, reduces risks from aerial applications. Similarly, using coarser sprays and lowering boom height for groundboom sprayers or applications to denser crop canopies with airblast sprayers lowers risk concerns.

Table 9.1. Summary of Spray Drift Buffers Assuming Screening-Level Droplet Sizes, Canopy Densities, and Boom Heights[1] by Agricultural Crop for Bifenthrin[2].

Crop	Application rate (lb ai/A)	Distance From Field Edge	Adult Dermal MOEs[2]			Children 1 < 2 years old Combined Dermal + Incidental Oral MOEs[2]		
			LOC = 100			LOC = 300		
		(Feet)	Aerial	Groundboom	Airblast	Aerial	Groundboom	Airblast
Citrus	0.5	0	N/A	1,000	N/A	N/A	310	400
Tobacco	0.40	0	910	1,300	1,600	**280**	390	500
		10	N/A	N/A	N/A	350	N/A	N/A
All other crops/ rates	0.30 – 0.041	0	1,200 – 16,000			370 – 4,900		

1 Risk estimates presented assuming screening-level droplet sizes (fine to medium for aerial applications; very fine to fine for groundboom applications), sparse canopies for airblast applications; and high booms for groundboom applications. Assuming coarser droplet sizes and lower booms will reduce risks.

2 Algorithms, assumptions, and calculations for the non-occupational spray drift assessment are provided in Appendix D of D440261. "N/A" provided when equipment not applicable based on the use pattern or when MOEs are not of concern at distances closer to the field edge (i.e., if risk estimates are not of concern at the field edge, additional risk estimates are not presented for 10 ft from the field edge).

10.0 Cumulative Exposure/Risk Characterization

The Agency is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The Agency has determined that the pyrethroids and pyrethrins share a common mechanism of toxicity (http://www.regulations.gov; EPA-HQ-OPP-2008-0489-0006). As explained in that document, the members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. In 2011, after establishing a common mechanism grouping for the pyrethroids and pyrethrins, the Agency conducted a cumulative risk assessment (CRA) which is available at http://www.regulations.gov; EPA-HQ-OPP-2011-0746. In that document, the Agency concluded that cumulative exposures to pyrethroids (based on pesticidal uses registered at the time the assessment was conducted) did not present risks of concern. For information regarding EPA's efforts to evaluate the risk of exposure to this class of chemicals, refer to https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids.

Since the 2011 CRA, for each proposed pyrethroid or pyrethrins use, the Agency has conducted a qualitative screen to evaluate any potential impacts on the CRA prior to registration of that use. For the proposed new uses of bifenthrin, the Agency has conducted an additional screen, taking into account all previously approved uses and the proposed new uses.

The proposed new uses/crop group conversions of bifenthrin on avocado, *Brassica* leafy subgroup 4-16B, caneberry subgroup 13-07A (crop group conversion), citrus group 10-10 (crop group conversion), low growing berry subgroup 13-07 G, peach subgroup 12-12B, pepper/eggplant subgroup 8-10B, pome fruit 11-10 (except mayhaw), pomegranate, small vine climbing subgroup 13-07F, tomato subgroup 8-10A, and tree nut group 14-12 (crop group conversion), will not significantly impact the cumulative assessment because dietary exposures make a minor contribution to the total pyrethroid exposure relative to residential exposures in the 2011 cumulative risk assessment. Therefore, the results of the 2011 CRA are still valid and there are no cumulative risks of concern for the pyrethroids/pyrethrins.

11.0 Occupational Exposure/Risk Characterization

11.1 Short-/Intermediate-Term Occupational Handler Exposure and Risk Estimates

Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, occupational handler exposure is expected from the registered uses of bifenthrin. The quantitative exposure/risk assessment developed for occupational handlers is based on the representative scenarios further detailed in Appendix F (Tables F.3 and F.4). Applying RTU total release foggers in greenhouses is expected to amount in negligible dermal and inhalation exposures for occupational handlers; therefore, has not been quantitatively assessed.

Occupational Handler Non-Cancer Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor is detailed below on an individual basis. A screening-level approach was used for this assessment of occupational exposures by evaluation of the maximum application rate for the representative occupational handler exposure scenarios of bifenthrin.

Application Rate: The registered application rates for bifenthrin are listed in Appendix F (Table F.3. and Table F.4). The proposed application rates for bifenthrin are listed in Table F.1. The maximum single application rate for each crop scenario was assessed based on the proposed product labels and the representative registered labels. Lower application rates were only assessed if the maximum rates resulted in risk estimates of concern with baseline attire or label-specified PPE (baseline attire and chemical resistant gloves).

Unit Exposures: It is the policy of HED to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include PHED 1.1, the Policy 14 for Seed Treatment, AHETF database, the ORETF database, or other registrant-submitted occupational exposure studies. Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as "unit exposures," are outlined in the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table,[18]" which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at the Agency website[19].

The registered labels indicate that bifenthrin may be used both commercially and on-farm to treat seed prior to planting. There are no surrogate data for on-farm seed treatment with liquid formulation (data only available for dust formulations). Therefore, the unit exposures assigned to the mixing/loading liquid formulation scenario derived from AHETF (MRID 47947802)/PHED were used as a surrogate for on-farm seed treatment activities (baseline dermal UE = 220 µg/lb ai, baseline inhalation UE = 0.219 µg/lb ai).

For the dry bulk fertilizer scenarios, HED assumes a closed mixing/loading scenario for commercial impregnation of dry bulk fertilizer, and an open mixing/loading scenario for grower-owned (i.e., on-farm) equipment impregnation of dry bulk fertilizer. For all applications of dry bulk fertilizer, HED assumes the use of an open-cab tractor spreader.

As HED does not have aircraft-specific exposure data, the Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1) indoor exposure data has been used to assess applications to military aircraft cabin, crew, and cargo areas for the purposes of this assessment.

Area Treated or Amount Handled: The area treated/amount handled for non-seed treatment uses are based on ExpoSAC Policy 9.1. For assessing seed treatment and seed planting activities, amount treated was taken from HED ExpoSAC Policy 15, HED ExpoSAC Policy 15.1, phase 2 of the AHETF seed treatment survey (MRID 49185401) and the BEAD memo: "Acres Planted per Day and Seeding Rates of Crops Grown in the United States." The amount of active ingredient handled depends on the application rate (lb ai/lb seed) and the pounds of seed treated in a day (or the pounds of seed that can be planted in a day).

HED does not have chemical-specific data regarding the amounts handled for the mixing/loading or area treated for the application of bifenthrin-impregnated dry bulk fertilizer. The

[18] Available: https://www.epa.gov/sites/production/files/2016-11/documents/handler-exposure-table-2016.pdf
[19] Available: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data

mixing/loading processing rate for commercial impregnation of dry bulk fertilizer has been estimated to be 960 tons of fertilizer processed per 8 hour day based on information supplied by a registrant concerning the chemical alachlor (as referenced in its reregistration eligibility decision (RED) document[20]). Mixing/loading for on-farm impregnation of dry bulk fertilizer was then assessed using an estimate of 160 acres/day. Application of dry bulk fertilizer was assessed assuming application to up to 320 acres/day for commercial equipment and 160 acres/day for grower-owned equipment.

Exposure Duration: HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Exposure duration is determined by many things, including the exposed population, the use site, the pest pressure triggering the use of the pesticide, and the cultural practices surrounding that use site. For most agricultural uses, it is reasonable to believe that occupational handlers will not apply the same chemical every day for more than a one-month time frame; however, there may be a large agribusiness and/or commercial applicators who may apply a product over a period of weeks (e.g., completing multiple applications for multiple clients within a region).

For bifenthrin, based on the existing and proposed uses, both short- and intermediate-term exposures are expected for occupational handlers because it could be applied multiple times per season to many registered crops. Bifenthrin is also registered for use in greenhouses, and while crops may be grown year round in greenhouses, occupational exposures are considered more like a series of short-term exposures, rather than a continuous long-term exposure. The single dose and repeat dosing bifenthrin studies show that repeat exposures do not result in lower PODs (i.e., there is no evidence of increasing toxicity with an increased duration of exposure). As such, the exposure assessments are conducted as a series of acute exposures, and the same endpoint is used regardless of duration. Therefore, the acute/single day assessments are protective of scenarios in which exposure occurs for multiple days.

Mitigation/Personal Protective Equipment: Estimates of dermal and inhalation exposure were calculated for various levels of PPE. Results are presented for "baseline," defined as a single layer of clothing consisting of a long sleeved shirt, long pants, shoes plus socks, no protective gloves, and no respirator, as well as baseline with various levels of PPE as necessary (e.g., gloves, respirator, etc.). The registered bifenthrin labels require baseline attire (long sleeved shirts, long pants, shoes, and socks) and in some cases PPE including chemical resistant gloves, protective eyewear, and a respirator. A respiratory protection device is required when working in a non-ventilated space. Exposure data for workers loading/applying, performing multiple activities, and planting treated seed is only available for occupational handlers wearing gloves.

Occupational Handler Non-Cancer Exposure and Risk Estimate Equations

The algorithms used to estimate non-cancer exposure and dose for occupational handlers can be found in (K. Rickard, D440261 and D441553, 07/19/2017).

Combining Exposures/Risk Estimates:

[20] http://archive.epa.gov/pesticides/reregistration/web/pdf/0063fact.pdf

A total aggregated risk index (ARI) was used since the LOC values for dermal exposure (100) and inhalation exposure (30) are different. The target ARI is 1; therefore, ARIs of less than 1 are risk estimates of concern. The aggregate risk index (ARI) was calculated as follows.

Aggregate Risk Index (ARI) = 1÷ [(Dermal LOC ÷ Dermal MOE) + (Inhalation LOC ÷ Inhalation MOE)]

Summary of Occupational Handler Non-Cancer Exposure and Risk Estimates

The inhalation and the majority of the dermal occupational handler risk estimates did not result in risk estimates of concern (dermal MOEs ≥ 100, inhalation MOEs ≥ 30, and ARI ≥ 1) with baseline attire for the registered and proposed uses of bifenthrin. All occupational handler risk estimates using maximum application rates for each scenario are presented in Appendix D. Dermal MOEs ranged from 32 to 550,000,000, inhalation MOEs ranged from 200 to 15,000,000, and ARIs ranged from 0.31 to 13,000. For those scenarios that resulted in risk estimates of concern with baseline attire, additional PPE was assessed. The scenarios that result in risk estimates of concern are as follows:

- Mixing/Loading liquids for aerial ultra-low volume (ULV) application to cotton (0.1 lb ai/A):
    - Baseline: Dermal **MOE = 47**, Inhalation MOE = 510, **ARI = 0.46**
    - Baseline + gloves Dermal MOE = 270, Inhalation MOE = 510, ARI = 2.3. Waterproof or chemical resistant gloves required by the representative labels evaluated (EPA Reg. Nos. 279-3108 and 279-3313).

- Mixing/Loading/Applying liquids with a mechanically pressurized handgun for soil at-plant applications to tuberous and corm vegetables (0.03 lb ai/gallon):
    - Baseline: Dermal MOE = **42**, Inhalation MOE = 320, ARI = **0.40**
    - Baseline + gloves: Dermal MOE = 130, Inhalation MOE = 320, ARI = 1.2. Waterproof or chemical resistant gloves are required by the representative labels evaluated (EPA Reg. Nos. 279-3313 and 279-3302).
- Mixing/Loading/Applying liquids with a mechanically pressurized handgun for soil at-plant applications to tobacco (0.04 lb ai/gallon):
    - Baseline: Dermal MOE = **32**, Inhalation MOE = 240, ARI = **0.31.**
    - Baseline + chemical resistant gloves: Dermal MOE = **93**, Inhalation MOE = 240, ARI = **0.83.**
    - Baseline + double layer of clothing + chemical resistant gloves: Dermal MOE = 140, Inhalation MOE = 240, ARI = 1.2.
    - The representative label evaluated (EPA Reg. No. 279-3332) requires occupational handlers to wear only baseline attire (long sleeved shirts, long pants, shoes, and socks).

The Agency matches quantitative occupational exposure assessment with appropriate characterization of exposure potential. While HED presents quantitative risk estimates for human flaggers where appropriate, agricultural aviation has changed dramatically over the past two decades. According the 2012 National Agricultural Aviation Association (NAAA) survey of their membership, the use of GPS for swath guidance in agricultural aviation has grown steadily from the mid 1990's. Over the same time period, the use of human flaggers for aerial pesticide applications has decreased steadily from ~15% in the late 1990's to only 1% in the most recent

(2012) NAAA survey. The Agency will continue to monitor all available information sources to best assess and characterize the exposure potential for human flaggers in agricultural aerial applications.

HED has no data to assess exposures to pilots using open cockpits. The only data available is for exposure to pilots in enclosed cockpits. Therefore, risks to pilots are assessed using the engineering control (enclosed cockpits) and baseline attire (long-sleeve shirt, long pants, shoes, and socks); per the Agency's Worker Protection Standard stipulations for engineering controls, pilots are not required to wear protective gloves for the duration of the application. With this level of protection, there are no risk estimates of concern for applicators.

Water-soluble packaging is an engineering control designed to prevent direct contact between users and the pesticide formulation in the packages, thereby reducing exposures. Users place the packets into water which dissolves the packaging, releasing the formulation into the water without exposure to significant dusts or liquid aerosols. The formulation within the packaging then mixes with the water so it can be applied as a liquid spray.

This risk assessment relies on a 2015 study by the AHETF that measured dermal and inhalation exposure for workers who mixed and loaded water-soluble packet pesticide products. This data is considered the most reliable data for conducting exposure and risk assessments for such products. During the initial stages of the AHETF field study, the AHETF identified work practices that the Agency agreed were inconsistent with the use of water-soluble packaging as an engineering control intended to reduce exposures. For example, AHETF observed that some workers placed the packets in removable baskets hanging from the open tank hatch and used streams of water from hoses or overhead recirculation systems as agitation methods to break open and dissolve the packaging, resulting in visible and substantial amounts of airborne powder and/or liquid aerosol where the mixer/loader was working. Current labels, including those under consideration in this risk assessment, are silent or unclear on the use of baskets in the hatch and methods of agitation.

The AHETF, in consultation with the Agency, California's Department of Pesticide Regulation (CDPR) and the Canadian Pest Management Regulatory Agency (PMRA), drafted a set of best practices for handling and adding water-soluble packets to spray tanks. The resulting AHETF "mixing/loading water-soluble packet" dataset excludes monitoring results for activities inconsistent with these practices. Commensurate with use of the new dataset, the Agency has since formatted those best practices into label language to be included on all water-soluble packet pesticide products. This revised language ensures that users know water-soluble packets are intended to dissolve in water via mechanical agitation and not to rupture them via streams of water or other means. In order to achieve the intended benefits from proper use of water-soluble packaging, these best practices should be incorporated directly on product labels, conflicting language should be removed from the same labels, and users should receive effective and timely training on the new procedures.

11.2 Short-/Intermediate-Term Post-Application Exposure and Risk Estimates

11.2.1 Dermal Post-Application Risk

A series of assumptions and exposure factors served as the basis for completing the occupational post-application risk assessments. Each assumption and factor is detailed below on an individual basis. Trunk-directed and soil-directed applications were not quantitatively assessed (0.6 lb ai/A and 0.5 lb ai/A for citrus) because they are not expected to result in residues on foliage.

Exposure Duration: HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Exposure duration is determined by many things, including the exposed population, the use site, the pest pressure triggering the use of the pesticide, and the cultural practices surrounding that use site. For most agricultural uses, it is reasonable to believe that occupational post-application workers will not apply the same chemical every day for more than a one-month time frame; however, there may be a large agribusiness and/or commercial applicators who may apply a product over a period of weeks (e.g., completing multiple applications for multiple clients within a region).

Transfer Coefficients: It is the policy of HED to use the best available data to assess post-application exposure. Sources of generic post-application data, used as surrogate data in the absence of chemical-specific data, are derived from ARTF exposure monitoring studies, and, as proprietary data, are subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting post-application exposure that are used in this assessment, known as "transfer coefficients," are presented in the ExpoSAC Policy 3[21]" which, along with additional information about the ARTF data, can be found at the Agency website[22]. Only the maximum/highest TCs were presented for each scenario.

Application Rate: The registered application rates for bifenthrin are listed in Appendix F (Tables F.1 and F.3).

Exposure Time: The average occupational workday is assumed to be 8 hours.

Dislodgeable Foliar Residues: As noted in K. Rickard (D440261 and D441553, 07/09/2017), a total of four chemical-specific DFR data sets have been submitted for bifenthrin for the following crops: cotton (MRID 421422-01), roses and chrysanthemums (MRID 449552-01), and strawberries (MRID 446844-01). The cotton DFR data was found to unacceptable for risk assessment due to QA/QC concerns (see Appendix G and K. Rickard, D440261 and D441553, 07/19/2017). The chrysanthemum and strawberry data were used in the occupational post-application assessment.

Turf Transferrable Residues: As noted in K. Rickard (D440261 and D441553, 07/09/2017), a TTR study is available for bifenthrin (MRID 449552-01), and these data were used in the occupational post-application assessment. A summary of the data is provided in Appendix G and K. Rickard (D440261 and D441553, 07/19/2017).

Occupational Post-Application Non-Cancer Dermal Risk Estimates

[21] Available: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data
[22] Available: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data

Using chemical-specific DFR and TTR data, the occupational dermal post-application MOEs are not of concern (LOC = 100) for the registered and proposed uses of bifenthrin. The occupational post-application MOEs representing the worst-case activity scenario for each crop range from 190 to 8,200. All post-application risk estimates using maximum application rates and TCs for each scenario are presented in Appendix D.

Restricted Entry Interval

Bifenthrin is classified as Toxicity Category III by the acute dermal route of exposure and Toxicity Category IV for acute eye irritation potential and skin irritation potential. Under the WPS for Agricultural Pesticides, active ingredients classified as acute toxicity categories III or IV result in risk estimates for these routes are assigned a 12-hour REI. There are no dermal post-application risk estimates of concern on the day of application for bifenthrin; therefore, the REI of 12 hours is adequate.

With regard to seed treatment, the potential for post-application exposures following the planting of bifenthrin-treated seeds is unlikely because sustained levels of contact with treated seed after it has been placed in the soil or other planting media would not be expected because no routine cultural practice required for the production of agricultural commodities involves such an activity, as defined in the no/low contact criteria in the Worker Protection Standard (WPS). Therefore, no quantitative post-application assessment is required for exposure to treated seeds that have already been planted. The labeling properly states the exception to the Agricultural Use Requirements REI of 12 hours.

11.2.2 Inhalation Post-Application Risk

There are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037). The Agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (https://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219). During Registration Review, the Agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for bifenthrin.

In addition, the Agency is continuing to evaluate the available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. Given these two efforts, the Agency will continue to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the Agency's risk assessments.

Although a quantitative occupational post-application inhalation exposure assessment was not performed, an inhalation exposure assessment was performed for occupational/commercial handlers. Handler exposure resulting from application of pesticides outdoors is likely to result in

higher exposure than post-application exposure. Therefore, it is expected that these handler inhalation exposure estimates would be protective of most occupational post-application inhalation exposure scenarios.

Furthermore, inhalation exposure during dusty mechanical activities such as shaking and mechanical harvesting is another potential source of post-application inhalation exposure. However, the airblast applicator scenario is believed to represent a reasonable worst case surrogate estimate of post-application inhalation exposure during these dusty mechanical harvesting activities. The non-cancer inhalation risk estimate for commercial airblast application is not of concern (i.e., MOE > 30).

The Worker Protection Standard for Agricultural Pesticides contains requirements for protecting workers from inhalation exposures during and after greenhouse applications through the use of ventilation requirements. [40 CFR 170.110, (3) (Restrictions associated with pesticide applications)]

Commercial applicators do not typically return to the treated areas after an indoor commercial pesticide application (sites such as warehouses, food handling establishments, and hotels, etc.) and thus an occupational post-application inhalation exposure assessment was not performed for commercial applicators.

For the seed treatment uses of bifenthrin, a post-application inhalation exposure assessment is not required as exposure is expected to be negligible. Seed treatment assessments provide quantitative inhalation exposure assessments for seed treaters and secondary handlers (i.e., planters). It is expected that these exposure estimates would be protective of any potential low-level post-application inhalation exposure that could result from these types of applications.

12.0 Incident and Epidemiological Data Review

HED has prepared a Tier I Incident and Epidemiology Report for bifenthrin entitled "Bifenthrin: Updated Tier I Review of Human Incidents and Epidemiology for Draft Risk Assessment" (S. Recore, *et al.*; D441154, 07/26/2017).

The bifenthrin Tier II Incident and Epidemiology Report reviews human observation data from a variety of sources including:

- Human incident (poisoning) data from the following sources:
  - OPP's IDS database,
  - The Center for Disease Control (CDC)/NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides,
  - the Agency-sponsored National Pesticide Information Center (NPIC), and
  - California's Pesticide Incident Surveillance Program (PISP),
- Epidemiological studies [Agricultural Health Study (AHS)].

HED found that the acute health effects reported for bifenthrin are consistent among the databases queried. These health effects primarily included neurological, respiratory, dermal and

gastrointestinal effects. HED did not identify any aberrant effects outside of those anticipated. These effects are generally mild/minor to moderate and resolve rapidly.

The available incident data from IDS, NPIC, SENSOR-Pesticides and California PISP suggest that most of the reported bifenthrin incidents involve homeowner exposures. In IDS, except for one incident with an unknown exposure scenario, all the reviewed incidents occurred in residential settings. Thirty-three percent (33%) of these exposures were due to homeowner mixing/loading and or applying a bifenthrin product. The remaining IDS incidents were associated with post-application exposures, contact with product, misuse, equipment malfunction, and bystander exposure. NPIC data show that residential post-application following a pest control operator (PCO) application of a bifenthrin product are responsible for the most reported incidents (19%). In SENSOR-Pesticides, data showed that 64% of the 277 reviewed cases occurred in residential settings. Finally, CA PISP data showed 72% of the 75 reviewed cases occurred in non-agricultural settings.

Although most bifenthrin cases reported to the SENSOR-Pesticides and California PISP databases were residential, both datasets did have several occupational incidents reported involving bifenthrin. Both SENSOR-Pesticides and PISP reported most occupational incidents occurred while conducting routine work, including fieldwork.

The bifenthrin incident trend, from 2004 to 2014, was reviewed. The number of reported incidents, which are primarily non-occupational cases, appear to remain steady from 2004 to 2014. In SENSOR-Pesticides, the trend line for all single ai bifenthrin cases reported to SENSOR-Pesticide from 1998 to 2011 shows a sharp increase from 1998 to 2007 then a gradual decline from 2008 to 2011. When looking at the single ai bifenthrin work-related cases only, there is a gradual increase from 1998 to 2011.

Published AHS studies investigating the association of bifenthrin with various health outcomes were reviewed. With respect to carcinogenic effects, no studies were investigated within the AHS for bifenthrin. For non-carcinogenic effects, a single AHS study (Hoppin et al. 2016) investigated the association between allergic and non-allergic wheeze relative to exposure to bifenthrin. No evidence of a significant positive association was observed for allergic and non-allergic wheeze relative to bifenthrin exposure. The epidemiology review found that there was no evidence to suggest a clear causal relationship between exposure to bifenthrin and the health outcomes investigated in the AHS studies reported here. The Agency will continue to monitor epidemiological data through the ongoing AHS, and further analyses will be undertaken if necessary as additional data becomes available.

13.0 References

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Appendix A. Toxicology Profile and Executive Summaries

A.1 Toxicology Data Requirements

The requirements (40 CFR 158.340) for the food uses of bifenthrin are in Table A.1. Use of the new guideline numbers does not imply that the new (1998) guideline protocols were used.

Table A.1. Toxicology Requirements for Bifenthrin.

Guideline Number and Toxicity Study	Required	Satisfied
870.1100 Acute Oral Toxicity	yes	yes
870.1200 Acute Dermal Toxicity	yes	yes
870.1300 Acute Inhalation Toxicity	yes	yes
870.2400 Primary Eye Irritation	yes	yes
870.2500 Primary Dermal Irritation	yes	yes
870.2600 Dermal Sensitization	yes	yes
870.3100 Oral Sub-chronic (Rodent)	yes	yes
870.3150 Oral Sub-chronic (Non-Rodent)	yes	yes
870.3200 21-Day Dermal	yes	yes
870.3250 90-Day Dermal	no	no[1]
870.3465 90/28-Day Inhalation	yes	yes
870.3700 Developmental Toxicity (Rodent)	yes	yes
870.3700 Developmental Toxicity (Non-rodent)	yes	yes
870.3800 Reproduction	yes	yes
870.4100 Chronic Toxicity (Rodent)	yes	yes
870.4100 Chronic Toxicity (Non-rodent)	yes	yes
870.4200 Oncogenicity (Rat)	yes	yes
870.4200 Oncogenicity (Mouse)	yes	yes
870.4300 Chronic/Oncogenicity	yes	yes
870.5100 Mutagenicity: Gene Mutation - bacterial	yes	yes
870.5300 Mutagenicity: Gene Mutation - mammalian	yes	yes
870.5375 Mutagenicity: Structural Chromosomal Aberrations	yes	yes
870.5385 Mutagenicity: Structural Chromosomal Aberrations	yes	yes
870.5500 Mutagenicity: Other Genotoxic Effects	yes	yes
870.5550 Mutagenicity: Other Genotoxic Effects	yes	yes
870.6100 Acute Delayed Neurotoxicity (Hen)	no	-
870.6100 90-Day Neurotoxicity (Hen)	no	-
870.6200 Acute Neurotoxicity Screening Battery (Rat)	yes	yes
870.6200 90 Day Neurotoxicity. Screening Battery (Rat)	yes	yes
870.6300 Developmental Neurotoxicity	yes	yes
870.7485 General Metabolism	yes	yes
870.7600 Dermal Penetration	yes	yes
870.7800 Immunotoxicity	no[2]	no

1 D. Smegal, TXR# 0056209, 04/26/2012.
2 U. Habiba, TXR# 0056830, 11/13/2013, update to U. Habiba, TXR# 0056729, 08/12/2013.

A.2 Toxicity Profiles

Table A.2.1. Acute Toxicity Profile – Bifenthrin.				
Guideline No.	**Study Type**	**MRID No.**	**Results**	**Toxicity Category**
870.1100	Acute oral toxicity	00132519	LD_{50} = 70.1 mg/kg (♂); 53.8 mg/kg (♀)	II
870.1200	Acute dermal toxicity	00132520	LD_{50} > 2,000 mg/kg	III
870.1300	Acute inhalation toxicity	46008101	LC_{50}=1.01 mg/L (combined value, Male is 1.1 & Female is 0.8 mg/L) Heated to 100° C for testing	III
870.2400	Primary eye irritation	00132522	Non-irritant	IV
870.2500	Primary dermal irritation	00132521	Non-irritant	IV
870.2600	Dermal sensitization	00132523	Not a sensitizer	N/A

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
Acute and Sub-chronic Toxicity			
Special Study	47885701	Wolansky Study (2006) Acute Oral Toxicity in Long Evans Rats	$BMDL_{1SD}$ = 3.1 mg/kg BMD_{1SD} = 4.1 mg/kg based on decreased locomotor activity 0, 0.03, 0.1, 1.0, 4.0, 8.0, 12.0, 16.0, 24.0, 28.0 mg/kg via gavage in corn oil (1 mL/kg) **Classification: Acceptable, Non-Guideline**
Special Study	47050504, 47050505	Weiner/WIL Study (2009) Acute Oral Toxicity in Rats	$BMDL_{20}$ = 0.4 mg/kg BMD_{20} = 14.3 mg/kg based on multiple FOB changes 0, 40, 55 mg/kg via gavage in corn oil (5 mL/kg) **Classification: Acceptable, Non-Guideline**
870.3100	00141199	90-Day Oral Toxicity - Rat (1984)	NOAEL = 3.8 mg/kg/day (males); 4.3 mg/kg/day (females) LOAEL = 7.5 mg/kg/day (males), 8.5 mg/kg/day (females), based on increased incidence of tremors. **Classification: Acceptable-Guideline**
870.3150	00141200	90-Day Oral Toxicity - Dog (1984)	NOAEL = 2.21 mg/kg/day (males and females)

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
			LOAEL = 4.42 mg/kg/day (males and females) based on increased incidence of tremors. **Classification: Acceptable-Guideline**
Prenatal Developmental Toxicity			
870.3700	00154482	Developmental Toxicity (Gavage) - Rat (1983) Range-finding study	Maternal Toxicity NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. Developmental Toxicity NOAEL = not determined (fetuses not examined) LOAEL = not determined (fetuses not examined) **Classification: Acceptable-Guideline**
870.3700	00141201	Developmental Toxicity (Gavage) - Rat (1984)	Maternal Toxicity NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. Developmental Toxicity NOAEL = 1.77 mg/kg/day LOAEL = Not Observed **Classification: Acceptable-Guideline**
870.3700	45352301	Developmental Toxicity (Dietary) - Rat (2001)	Maternal Toxicity NOAEL = 7.1 mg/kg/day LOAEL = 15.5 mg/kg/day based clinical signs and decreased food consumption, body weight gains, and body weight gains adjusted for gravid uterine weight. Developmental Toxicity NOAEL = 15.5 mg/kg/day LOAEL = not observed. **Classification: Acceptable-Guideline**
870.3700	00145997	Developmental Toxicity - Rabbit (1984)	Maternal Toxicity NOAEL = 2.36 mg/kg/day LOAEL = 3.5 mg/kg/day based on treatment-related head and forelimb twitching. Developmental Toxicity NOAEL = greater than 7 mg/kg/day LOAEL = not observed **Classification: Acceptable-Guideline**
Reproductive Toxicity			

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
870.3800	00157225	Multigeneration Reproductive Toxicity - Rat (1986)	Parental/Systemic Toxicity NOAEL = 3.0 mg/kg/day for females and 5.0 mg/kg/day for males LOAEL = 5.0 mg/kg/day for females, based on tremors and decreased body weight; not observed for males. Reproductive/offspring Toxicity NOAEL =5.0 mg/kg/day. LOAEL = not observed. **Classification: Acceptable-Guideline**
Chronic Toxicity/Carcinogenicity			
870.4100	00163065	Chronic Toxicity (1 Year) - Dog (1985)	NOAEL = 1.3 mg/kg/day (males and females) LOAEL = 2.7 mg/kg/day (males and females) based on increased incidence of tremors. Classification: Acceptable-Guideline
870.4300	00157226	Combined Chronic Toxicity/Carcinogenicity - Rat (1986)	NOAEL = 3.0 mg/kg/day (females); 4.7 mg/kg/day (males) LOAEL = 6.1 mg/kg/day (females), based on increased incidence of tremors; 9.7 mg/kg/day (males), based on increased incidence of tremors. Carcinogenicity - No conclusive evidence of carcinogenic potential. **Classification: Acceptable-Guideline**
870.4200	00157227	Carcinogenicity - Mice (1986)	NOAEL = 6.7 mg/kg/day (males); 8.8 mg/kg/day (females) LOAEL = 25.6 mg/kg/day (males) and 32.7 mg/kg/day (females), based on increased incidence of tremors. Carcinogenicity - carcinogenic potential was evidenced by a dose-related increase in the incidence of hemangiopericytoma in the urinary bladder, a significant dose-related trend for combined hepatocellular adenomas and carcinomas in males, and a significantly higher incidence of combined lung adenomas and carcinomas in females. **Classification: Acceptable-Guideline**
Neurotoxicity			
870.6200a	44862102	Acute Neurotoxicity - Rat	NOAEL = 35 mg/kg (32.8 mg ai/kg/day). LOAEL = 75 mg/kg (70.3 mg ai/kg/day) based on mortality (females only), clinical and FOB findings and differences in motor activity. No vehicle utilized and heated to 80° C to liquefy. **Classification: Acceptable-Guideline**

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
870.6200b	44862103	Sub-chronic Neurotoxicity - Rat	NOAEL = 50 ppm (equivalent to 2.9 mg/kg/day in males and 3.7 mg/kg/day in females). LOAEL =100 ppm (equivalent to 6.0 mg/kg/day in males and 7.2 mg/kg/day in females) based on neuromuscular findings (tremors, changes in grip strength and landing foot-splay). **Classification: Acceptable-Guideline**
870.6300	46750501	Developmental Neurotoxicity - Rat	**Maternal** NOAEL = 3.6 mg/kg/day during gestation and 8.3 mg/kg/day during lactation, LOAEL = 7.2 mg/kg/day during gestation and 16.2 mg/kg/day during lactation based on clinical signs of neurotoxicity (tremors, clonic convulsions, and increased grooming counts). **Developmental** NOAEL =3.6 mg/kg/day during gestation and 8.3 mg/kg/day during lactation. **Developmental** LOAEL = 7.2 mg/kg/day during gestation and 16.2 mg/kg/day during lactation based on clinical signs of neurotoxicity (increased grooming counts).
Dermal Toxicity			
870.3200	00141198	Dermal Toxicity - Rabbit	NOAEL = 88 mg ai/kg/day (males and females) LOAEL = 442 mg ai/kg/day (males and females), based on loss of muscle coordination and increased incidence of tremors.
870.3200	45280501	Dermal Toxicity - Rat	NOAEL = 47 mg ai/kg/day (males and females) $BMDL_{10}$=96.3 mg/kg/day LOAEL = 93 mg ai/kg/day (males and females), based on staggered gait (M) and exaggerated hind limb flexion (F) BMD_{10}=187.0 mg/kg/day, based on exaggerated hind limb flexion
Inhalation Toxicity			
870.3465	49462201	Inhalation toxicity - rat	LOAEL = 0.0196 mg/L/day based on increased tremors and increased respiration rate NOAEL = 0.0059 mg/L/day

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
Metabolism and Pharmacokinetics			
870.7485	00163067 40415102	Metabolism - Rat	Very little of the administered radioactive dose was expired as $^{14}C\text{-}CO_2$ (0.028% for males and 0.053% for females). The majority (about 70%) of the administered radioactivity was found in the feces with about 20% in the urine. A complication of this study is that males were administered a radioactive dose with the label in the acid position, while females were administered a radioactive dose with the label in the alcohol position. This could make comparisons between males and females difficult. Despite the difference in ^{14}C- labelling position in the bifenthrin administered to males and females, the study is acceptable. This conclusion is based on the fact that most (>90%) of the radioactivity was eliminated via the urine and feces, with no significant differences between the sexes in this respect. Further, there were no significant differences between dosage groups in percentages excreted. This suggests that most of the compound is excreted with little or no change, or in a form incorporating both of the labeled sites. The results also show that females retained slightly more radioactivity in their bodies (particularly in adipose tissue) than did males, particularly at the high-dose. Labeling of the material given to the females was in the biphenyl group, and, given a splitting of the molecule between the two labeling sites, this would have tended to give a more lipophilic radiolabeled residue. **Classification: Acceptable-Guideline**
870.7485	00163069	Metabolism - Rat	Plasma radioactivity in the low-dose (4 mg/kg) animals after dosing slowly rose, indicating a slow rate of absorption from the gastrointestinal tract. The half-life of absorption was calculated to be about 1.5 hours, with a lag-time of 0.5 hours following first order kinetics. Radioactivity peaked in plasma for low-dose animals in 4 hours. The elimination of ^{14}C-bifenthrin from the plasma was equally slow, with significant radioactivity still remaining in blood at 72 hours. Plasma radioactivity in the high-dose (35 mg/kg) animals appeared to follow a similar course as seen in the low-dose animals. The peak radioactivity for the high-dose group appeared to be somewhat delayed, peaking at about 6 hours. Significant radioactivity still remained after 72 hours in the high-dose animals. **Classification: Acceptable-Guideline**
870.7485	00163070	Metabolism - Rat	The major metabolic route of radiolabeled bifenthrin appeared to be hydrolysis of the ester linkage with oxidation of the resulting alcohol to the acid. Protein binding of radioactive components or metabolites appears to increase with time.

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
			Classification: Acceptable-Guideline
870.7485	00163071	Metabolism - Rat	Fat and skin half-lives were the longest with half-lives of 51 and 50 days, respectively. The half-lives for ovaries, liver, kidneys and sciatic nerve were 37.4, 19.0, 28.5, and 42 days, respectively. Radioactive components were measured in fat at numerous time intervals, before and after daily dosing. The major component in fat is parent compound with a half-life of 47.5 days. Other unidentified components included a somewhat polar ($R_f = 0.65$) compound and two other relatively minor components. **Classification: Acceptable-Guideline**
870.7485	00163066	Metabolism - Rat	Within 7 days, nearly all bifenthrin and/or metabolites were excreted in either urine or feces. The majority of radioactivity was excreted in the feces within 48 hours. Tissues that retained bifenthrin and/or metabolites beyond 7 days included fat and skin in males and females, and gonads in females. **Classification: Unacceptable-Guideline**. Although the number of animals/group in this study was 3, and not 5/sex/group as recommended by guidelines, and a quality assurance statement was lacking, the results of this study provide useful information.
870.7485	40415100	Metabolism - Rat	Results showed minimal breakage of the ester linkage of the parent compound in the material eliminated via the feces in the period of 0-48 hours after dosage, when most of the administered radioactivity is identified as coming from unmodified parent compound. However, the material was subsequently eliminated, although a relatively small proportion of the administered dose appears to have undergone more modification. Since a greater proportion of the radioactivity was eliminated via the feces in the period of 48-168 hours in the form of 2-Methyl-3-phenylbenzyl alcohol and 2-Methyl-3-phenylbenzoic acid than the parent compound, this is evidence that extensive breakage of the ester linkage does occur, either in the material retained in the intestines for more than 46 hours, or in the material absorbed and subsequently eliminated via the feces. **Classification: Unacceptable-Guideline**. While this study is limited, it does provide some insight into the incomplete absorption of bifenthrin from the intestine, and the lack of modification of most of the unabsorbed material, particularly that eliminated via the feces during the period of 0-48 hours. However, the metabolism of the absorbed compound (radioactivity primarily excreted via the urine, despite differences in labeling) is less clear.
870.7485	00163068	Metabolism - Rat	The results of the study demonstrated that the majority of radioactivity excreted in the feces was the parent compound and its intact hydroxylated

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
			metabolites. Much of the radioactivity excreted in urine was hydrolytic and hydrolytic/oxidative degradation products of the parent compound. **Classification: Unacceptable-Guideline.**
Dermal Penetration			
870.7600	41917503	Dermal Penetration - Rats	For animals in group A, means of 4.6, 14.2, 12.8 and 14.7% total dose were recovered from the skin at 0, 4, 10 and 24 hours post-dose; corresponding percentages in the wash were 94.6, 80.8, 78.6 and 70%. For animals in group B, means of 20.0, 37.9, 42.0 and 41.2% remained (and were recovered from) the skin at 0, 4, 10 and 24 hours post-dose; corresponding percentages in the wash were 73.9, 50.6, 41.3 and 37.7% respectively. This dermal absorption study is classified as **acceptable**. However, because only one dose was used, this study, by itself, does not satisfy the guideline requirement for a dermal penetration study (85-2) in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.
870.7600	41917502	Dermal Penetration - Rats	Means of 96.83, 84.75, 76.86 and 72.88% of the radioactivity were recovered in the skin wash at 0, 4, 10 and 24 hours post dosage, respectively. By the time the 4-hour post-dose and later skin samples were collected the emulsifying solvents had evaporated. Means of 4.04, 12.00, 16.55 and 19.44% total dose were recovered from the washed skin of the application site at 0, 4, 10 and 24 hours respectively; corresponding mean percentages recovered from the carcass were 0.09, 0.87, 0.85 and 1.67%. Mean percentages recovered in urine and feces were 0, 0.14, 0.43 and 3.23%. This dermal absorption study is classified as **acceptable**. However, because only one dose was used, this study, by itself, does not satisfy the guideline requirement for a dermal penetration study (85-2) in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.
870.7600	00163072	Dermal Penetration - Rats	In general, only very small amounts of radioactivity were present in blood, excrement, and carcasses, with almost all (approximately 99%) of the absorbed radioactivity localized in skin at the application site, and in the skin adjacent to the application site. Average percentages of FMC 54800 dosages absorbed at 10 hours were 55.8%, 54.1%, and 37.5% for the 49.2, 514 and 5253 µg/rat groups respectively.

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline Number	**MRID No.**	**Study Type**	**Results**
			Corresponding percentages for the 3 groups at the 0.5 hour sacrifice were 54.6%, 56.4%, and 52.5%, so the percentage absorption of FMC 54800 did not seem to depend on time-to-sacrifice. At 10 hours and the lowest dose level, the percentages present were as follows: excreta: <0.44%; carcass: <1.8%; skin at application site: 50.3%; skin adjacent to application site: 5.5%. At 10 hours and the highest dose level, the percentages of total dose present were as follows: excreta: 0.07%; carcass: 0.5%; skin at application site: 34.6%; skin adjacent to application site: 2.7 %. **Classification:** This dermal absorption study is classified as **acceptable**. However, by itself, does not satisfy the guideline requirement for a dermal penetration study (85-2) in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.
870.7600	41284202	Dermal Penetration - Rats	The report states that at 24 hours post dose, 5.11% of the dose was absorbed (application-site skin + carcass + urine + feces) in this second trial. However, it is noted that there was poor recovery (68% of the total dose) from one of the rats (C32545) sacrificed at 24 hours in the second trial; disregarding the findings from this one animal then the mean value of the dose that was absorbed was 5.88%, and this can be taken as a reasonable estimate of the dermal absorption at this dose level. This dermal absorption study is classified as **acceptable**. However, because only one dose was used, this study, by itself, does not satisfy the guideline requirement for a dermal penetration study (85-2) in the rat for technical bifenthrin (FMC 54800). However, it can be used, in conjunction with other dermal penetration studies, as supporting data for the purposes of registration and/or reregistration of products containing or consisting of bifenthrin.

A.3 Bifenthrin BMD Analysis for the 21-Day Dermal Study

Bifenthrin BMD Analysis: 21-Day Rat Dermal Study – MRID 45280501

BMDS 2.1.1: Dichotomous – multistage. Extra Risk BMR at 10%
Endpoint: Exaggerated hind limb flexion in females

BMD Results:

```
BMD =        187.052 mg/kg/day

BMDL =        96.2927 mg/kg/day
```

Calculations:

```
 ======================================================================
        Multistage Model. (Version: 3.2;  Date: 05/26/2010)
        Input Data File: C:/Usepa/BMDS212/Data/mst_testrundichotomous_Opt.(d)
        Gnuplot Plotting File:  C:/Usepa/BMDS212/Data/mst_testrundichotomous_Opt.plt
                                                  Wed Apr 06 12:01:44 2011
 ======================================================================

 BMDS_Model_Run
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

   The form of the probability function is:

   P[response] = background + (1-background)*[1-EXP(
                 -beta1*dose^1-beta2*dose^2)]

   The parameter betas are restricted to be positive

   Dependent variable = Effect
   Independent variable = Dose

 Total number of observations = 5
 Total number of records with missing values = 0
 Total number of parameters in model = 3
 Total number of specified parameters = 0
 Degree of polynomial = 2


 Maximum number of iterations = 250
 Relative Function Convergence has been set to: 1e-008
 Parameter Convergence has been set to: 1e-008


                  Default Initial Parameter Values
                     Background =    0.0031824
                        Beta(1) =  0.000548172
                        Beta(2) =            0


           Asymptotic Correlation Matrix of Parameter Estimates

           ( *** The model parameter(s)  -Background    -Beta(2)
                 have been estimated at a boundary point, or have been specified by
the user,
                 and do not appear in the correlation matrix )

                Beta(1)
```

```
   Beta(1)            1


                                Parameter Estimates

                                                          95.0% Wald Confidence
Interval
       Variable         Estimate        Std. Err.     Lower Conf. Limit   Upper Conf.
Limit
     Background                0            *                *                  *
        Beta(1)      0.000563269            *                *                  *
        Beta(2)                0            *                *                  *

* - Indicates that this value is not calculated.

                        Analysis of Deviance Table

       Model      Log(likelihood)  # Param's  Deviance  Test d.f.   P-value
     Full model        -9.98095         5
   Fitted model        -10.5726         1       1.18324      4          0.8809
  Reduced model        -16.2541         1       12.5464      4         0.01372

           AIC:         23.1451

                                 Goodness  of  Fit
                                                                      Scaled
     Dose     Est._Prob.    Expected    Observed     Size       Residual
  ----------------------------------------------------------------------
    0.0000     0.0000         0.000     0.000          10        0.000
   23.0000     0.0129         0.129     0.000          10       -0.361
   47.0000     0.0261         0.261     0.000          10       -0.518
   93.0000     0.0510         0.510     1.000          10        0.704
  932.0000     0.4084         4.084     4.000          10       -0.054

 Chi^2 = 0.90      d.f. = 4        P-value = 0.9250


   Benchmark Dose Computation

Specified effect =            0.1

Risk Type        =      Extra risk

Confidence level =           0.95

             BMD =        187.052

            BMDL =        96.2927

            BMDU =        598.842

Taken together, (96.2927, 598.842) is a 90     % two-sided confidence
interval for the BMD
```

Appendix B. Physical/Chemical Properties

Table B. Physicochemical Properties of Bifenthrin		
Parameter	**Value**	**Reference**
Melting point/range	68-70.6 °C	Product Chemistry Chapter of TRED (D283808, 08/21/2002, S. Levy)
pH	NA	
Density	1.26 g/mL (24 °C; true particle density)	
Water solubility	<0.1 g/L	
Solvent solubility	8.9 g/100 mL in heptane and methanol; 125 g/100 mL in acetone, chloroform, ether, methylene chloride, and toluene	
Vapor pressure	2.41×10^{-5} (25 °C)	
Dissociation constant, pK_a	NA	
Octanol/water partition coefficient, $Log(K_{OW})$	$>1 \times 10^{6}$	
UV/visible absorption spectrum	NA	

Appendix C. Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from PHED 1.1; the AHETF database; the Outdoor Residential Exposure Task Force (ORETF) database; the ARTF database; ExpoSAC Policy 14 (SOPs for Seed Treatment); the Residential SOPs (indoor environments, gardens and trees, lawns and turf, and pets), and scenario specific studies (MRIDs 44339801), are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency website[23].

[23] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data and https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-post-application-exposure

Appendix D. Occupational Exposure/Risk Summary Tables

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures[3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose[4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
Mixer/Loader										
Mixing/Loading Granules for Aerial Application	Field crop, typical	0.1 lb ai/acre	350 acres	8.4	1.7	0.0037	26,000	0.00074	1,400	40
	Field crop, high-acreage	0.1 lb ai/acre	1200 acres	8.4	1.7	0.013	7,600	0.0026	410	12
Mixing/Loading Granules for Tractor-Drawn Spreader Applications	Sod	0.4 lb ai/acre	80 acres	8.4	1.7	0.0034	29,000	0.00068	1,500	43
	Field crop, typical	0.3 lb ai/acre	80 acres	8.4	1.7	0.0025	38,000	0.00051	2,100	59
	Field crop, high-acreage	0.1 lb ai/acre	200 acres	8.4	1.7	0.0021	46,000	0.00043	2,500	71
Mixing/Loading Liquids for Aerial Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	220	0.219	0.19	500	0.00019	5,500	4.9
	Sod	0.21 lb ai/acre	350 acres	220	0.219	0.203	470	0.000201	5,200	4.6
	Field crop, typical	0.3 lb ai/acre	350 acres	220	0.219	0.29	330	0.00029	3,600	3.2
	Field crop, high-acreage	0.2 lb ai/acre	1200 acres	220	0.219	0.66	150	0.00066	1,600	1.5
	Field crop, high-acreage (ULV; Cotton only)	0.1 lb ai/acre	7500 acres	220	0.219	2.06	**47**	0.0021	510	**0.46**
				37.6 (gloves)		0.35	270			2.3
	Christmas Tree farm	0.1 lb ai/acre	1200 acres	220	0.219	0.33	290	0.00033	3,200	2.8
Mixing/Loading Liquids for Airblast Application	Nursery (ornamentals, vegetables, trees, container stock)	0.125 lb ai/acre	20 acres	220	0.219	0.0069	14,000	0.0000069	150,000	140
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	220	0.219	0.022	4,400	0.000022	48,000	43
	Christmas Tree farm	0.1 lb ai/acre	40 acres	220	0.219	0.011	8,800	0.000011	95,000	86
Mixing/Loading Liquids for Chemigation Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	220	0.219	0.19	500	0.00019	5,500	4.9
	Sod	0.21 lb ai/acre	350 acres	220	0.219	0.203	470	0.000201	5,200	4.6
	Field crop, typical	0.3 lb ai/acre	350 acres	220	0.219	0.29	330	0.00029	3,600	3.2
	Field crop, high-acreage	0.2 lb ai/acre	350 acres	220	0.219	0.19	500	0.00019	5,500	4.9
Mixing/Loading Liquids for	Nursery (ornamentals, vegetables, trees, container stock)	0.125 lb ai/acre	60 acres	220	0.219	0.021	4,700	0.000021	51,000	46

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures[3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose[4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
Groundboom Application	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.125 lb ai/acre	60 acres	220	0.219	0.021	4,700	0.000021	51,000	46
	Sod	0.21 lb ai/acre	80 acres	220	0.219	0.046	2,100	0.000046	23,000	20
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	220	0.219	0.022	4,400	0.000022	48,000	43
	Orchard/Vineyard (Citrus)	0.5 lb ai/acre	40 acres	220	0.219	0.056	1,700	0.000056	19,000	17
	Field crop, typical	0.3 lb ai/acre	80 acres	220	0.219	0.066	1,500	0.000066	16,000	15
	Field crop, high-acreage	0.2 lb ai/acre	200 acres	220	0.219	0.11	880	0.00011	9,500	8.6
Mixing/Loading WSP for Aerial Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	8,800	0.0023	460	13
	Field crop, typical	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	8,800	0.0023	460	13
	Field crop, high-acreage	0.1 lb ai/acre	1200 acres	12.5 (EC)	2.6 (EC)	0.019	5,100	0.0039	270	7.7
Mixing/Loading WSP for Chemigation Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	8,800	0.0023	460	13
	Field crop, typical	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	8,800	0.0023	460	13
Mixing/Loading WSP for Groundboom Application	Orchard/Vineyard	0.2 lb ai/acre	40 acres	12.5 (EC)	2.6 (EC)	0.0013	77,000	0.00026	4,000	110
	Orchard/Vineyard (Citrus)	0.5 lb ai/acre	40 acres	12.5 (EC)	2.6 (EC)	0.0031	31,000	0.00090	1,200	35
	Field crop, typical	0.2 lb ai/acre	80 acres	12.5 (EC)	2.6 (EC)	0.0025	39,000	0.00052	2,000	57
	Field crop, high-acreage	0.1 lb ai/acre	200 acres	12.5 (EC)	2.6 (EC)	0.0031	31,000	0.00065	1,600	46
Applicator										
Applying Sprays with Aerial Application Equipment	Orchard/Vineyard	0.2 lb ai/acre	350 acres	2.08 (EC)	0.0049 (EC)	0.0018	53,000	0.0000043	240,000	500
	Sod	0.21 lb ai/acre	350 acres	2.08 (EC)	0.0049 (EC)	0.0019	50,000	0.0000045	230,000	470
	Field crop, typical	0.3 lb ai/acre	350 acres	2.08 (EC)	0.0049 (EC)	0.0027	35,000	0.0000064	160,000	330
	Field crop, high-acreage	0.2 lb ai/acre	1200 acres	2.08 (EC)	0.0049 (EC)	0.0062	15,000	0.000015	71,000	140
	Field crop, high-acreage (ULV – Cotton only)	0.1 lb ai/acre	7500 acres	2.08 (EC)	0.0049 (EC)	0.020	4,900	0.000046	23,000	46
	Christmas Tree farm	0.1 lb ai/acre	1200 acres	2.08 (EC)	0.0049 (EC)	0.0031	31,000	0.0000074	140,000	290

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures[3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose[4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
Applying Sprays with Airblast Application Equipment	Nursery (ornamentals, vegetables, trees, container stock)	0.125 lb ai/acre	20 acres	1770	4.71	0.0554	1,700	0.00015	7,100	16
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	1770	4.71	0.18	540	0.00047	2,200	5
	Christmas Tree farm	0.1 lb ai/acre	40 acres	1770	4.71	0.089	1,100	0.00024	4,500	10
Applying Sprays with Groundboom Application Equipment	Nursery (ornamentals, vegetables, trees, container stock)	0.125 lb ai/acre	60 acres	78.6	0.34	0.0074	13,000	0.000032	33,000	120
	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.125 lb ai/acre	60 acres	78.6	0.34	0.0074	13,000	0.000032	33,000	120
	Sod	0.21 lb ai/acre	80 acres	78.6	0.34	0.017	5,800	0.000071	15,000	52
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	78.6	0.34	0.0079	12,000	0.000034	31,000	110
	Orchard/Vineyard (Citrus)	0.2 lb ai/acre	40 acres	78.6	0.34	0.020	4,900	0.000085	12,000	44
	Field crop, typical	0.3 lb ai/acre	80 acres	78.6	0.34	0.024	4,100	0.000102	10,000	37
	Field crop, high-acreage	0.2 lb ai/acre	200 acres	78.6	0.34	0.039	2,500	0.00017	6,200	22
Applying Granules with Aerial Application Equipment	Field crop, typical	0.1 lb ai/acre	350 acres	1.7 (EC)	1.3 (EC)	0.000744	130,000	0.00057	1,800	57
	Field crop, high-acreage	0.1 lb ai/acre	1200 acres	1.7 (EC)	1.3 (EC)	0.0026	38,000	0.0015	540	17
Applying Granules with a Tractor-Drawn Spreader	Sod	0.4 lb ai/acre	80 acres	9.9	1.2	0.0040	24,000	0.00048	2,200	56
	Field crop, typical	0.3 lb ai/acre	80 acres	9.9	1.2	0.0030	32,000	0.00036	2,900	74
	Field crop, high-acreage	0.1 lb ai/acre	200 acres	9.9	1.2	0.0030	32,000	0.00030	3,500	85
Flagger										
Flagging for Aerial Applications (Sprays)	Orchard/Vineyard	0.2 lb ai/acre	350 acres	11	0.35	0.0096	10,000	0.00031	3,400	53
	Sod	0.21 lb ai/acre	350 acres	11	0.35	0.0101	9,500	0.00032	3,300	51
	Field crop, typical	0.3 lb ai/acre	350 acres	11	0.35	0.015	6,600	0.00046	2,300	35
	Field crop, high-acreage	0.2 lb ai/acre	350 acres	11	0.35	0.0096	10,000	0.00031	3,400	53
	Field crop, typical	0.1 lb ai/acre	350 acres	2.75	0.15	0.0012	80,000	0.000066	16,000	320

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures[3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose[4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
Flagging for Aerial Applications (Granules)	Field crop, high-acreage	0.1 lb ai/acre	350 acres	2.75	0.15	0.0012	80,000	0.000066	16,000	320
Mixer/Loader/Applicator										
Mixing/Loading/Applying Liquids with a Backpack	Orchard/Vineyard	0.0125 lb ai/gallon	40 gallons	8260	2.58	0.052	1,900	0.000016	65,000	19
	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.00125 lb ai/gallon	40 gallons	13200	140	0.0083	12,000	0.000088	12,000	92
	Christmas Tree farm	0.005 lb ai/gallon	40 gallons	58400	69.1	0.15	660	0.00017	6,100	6.4
	Nursery (ornamentals, vegetables, trees, container stock)	0.00125 lb ai/gallon	40 gallons	58400	69.1	0.037	2,600	0.000043	24,000	25
Mixing/Loading/Applying Liquids with a Manually-pressurized Handwand	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.00125 lb ai/gallon	40 gallons	100000	30	0.063	1,500	0.000019	56,000	15
	Christmas Tree farm	0.005 lb ai/gallon	40 gallons	100000	30	0.25	390	0.000075	14,000	3.9
	Nursery (ornamentals, vegetables, trees, container stock)	0.00125 lb ai/gallon	40 gallons	100000	30	0.063	1,500	0.000019	56,000	15
	Mounds/nests	0.00078 lb ai/gallon	40 gallons	100000	30	0.039	2,500	0.000012	90,000	25
Mixing/Loading/Applying Liquids with a Mechanically-pressurized Handgun	Orchard/Vineyard	0.0125 lb ai/gallon	1000 gallons	6050	8.68	0.95	100	0.0014	770	0.96
	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.00125 lb ai/gallon	1000 gallons	3500	120	0.055	1,800	0.0019	560	9.2
	Christmas Tree farm	0.005 lb ai/gallon	1000 gallons	6050	8.68	0.38	250	0.00054	1,900	2.4
	Nursery (ornamentals, vegetables, trees, container stock)	0.00125 lb ai/gallon	1000 gallons	6050	8.68	0.095	1,000	0.0014	7,700	9.6
	Field crop, typical	0.01 lb ai/gallon	1000 gallons	6050	8.68	0.76	130	0.0011	960	1.2
				6050	8.68	2.3	**42**	0.0033	320	**0.40**

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).										
Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
		0.03 lb ai/gallon (Tuberous and Corm Vegetables only – Soil At-plant)		2050 (gloves)		0.77	130			1.2
		0.04 lb ai/gallon (Tobacco – Soil At-plant)		6050	8.68	3.03	**32**	0.0043	240	**0.31**
				2050 (gloves)		1.03	**93**			**0.83**
				1360 (DL/Gloves)		0.68	140			1.2
	Trees grown for non-commercial purposes (private lands, parks, or rangeland)	0.6 lb ai/A	5 acres	6050	8.68	0.23	420	0.00033	3,200	4.0
Mixing/Loading/Applying WSP Formulations with a Backpack	Orchard/Vineyard	0.0125 lb ai/gallon	40 gallons	8260	2.58	0.052	1,900	0.000016	65,000	19
Mixing/Loading/Applying WSP Formulations with a Mechanically-pressurized Handgun	Orchard/Vineyard	0.0125 lb ai/gallon	1000 gallons	6050	8.68	0.95	100	0.0014	770	0.96
	Field crop, typical	0.01 lb ai/gallon	1000 gallons	6050	8.68	0.76	130	0.0011	960	1.3
Loading/Applying Granule Formulations with a Rotary Spreader	Sod	0.4 lb ai/acre	5 acres	440	10	0.011	8,800	0.00025	4,200	54
Seed Treatment										
Loader/Applicator for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	125,000 lb seed	23 (gloves)	0.34	0.027	3,600	0.00040	2,600	25
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	23 (gloves)	0.34	0.027	3,600	0.00040	2,600	25
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	23 (gloves)	0.34	0.073	1,300	0.0011	970	9.3
	Dried Peas and Beans	0.00075 lb ai/lb seed	281,250 lb seed	23 (gloves)	0.34	0.061	1,600	0.00090	1,200	11
	Soybean	0.00075 lb ai/lb seed	281,250 lb seed	23 (gloves)	0.34	0.061	1,600	0.00090	1,200	11

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).										
Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
	Succulent Peas and Beans	0.00075 lb ai/lb seed	339,500 lb seed	23 (gloves)	0.34	0.073	1,300	0.0011	970	9.3
	Head and Stem Brassica	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	150,000	0.0000096	110,000	1,100
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	150,000	0.0000096	110,000	1,100
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	150,000	0.0000096	110,000	1,100
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	150,000	0.0000096	110,000	1,100
	Fruiting Vegetables (eggplant, bell and non-bell pepper, groundcherry, pepino, tomato, tomatillo)	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	150,000	0.0000096	110,000	1,100
Sewer for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	125,000 lb seed	0.0062	0.23	0.0000073	13,000,000	0.00027	3,900	130
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	0.0062	0.23	0.0000073	13,000,000	0.00027	3,900	130
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	0.0062	0.23	0.000020	4,900,000	0.00073	1,400	47
	Dried Peas and Beans	0.00075 lb ai/lb seed	281,250 lb seed	0.0062	0.23	0.000016	5,900,000	0.00061	1,700	57
	Soybean	0.00075 lb ai/lb seed	281,250 lb seed	0.0062	0.23	0.000016	5,900,000	0.00061	1,700	57
	Succulent Peas and Beans	0.00075 lb ai/lb seed	339,500 lb seed	0.0062	0.23	0.000020	4,900,000	0.00073	1,400	47
	Head and Stem Brassica	0.00075 lb ai/lb seed	3,000 lb seed	0.0062	0.23	0.00000018	550,000,000	0.0000065	160,000	5,300
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	0.0062	0.23	0.00000018	550,000,000	0.0000065	160,000	5,300
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	0.0062	0.23	0.00000018	550,000,000	0.0000065	160,000	5,300
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	3,000 lb seed	0.0062	0.23	0.00000018	550,000,000	0.0000065	160,000	5,300
	Fruiting Vegetables (eggplant, bell and non-bell pepper, groundcherry, pepino, tomato, tomatillo)	0.00075 lb ai/lb seed	3,000 lb seed	0.0062	0.23	0.00000018	550,000,000	0.0000065	160,000	5,300
Bagger for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	125,000 lb seed	9.1	0.16	0.011	9,000	0.00019	5,600	61
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	9.1	0.16	0.011	9,000	0.00019	5,600	61

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures[3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose[4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	9.1	0.16	0.029	3,300	0.00051	2,100	22
	Dried Peas and Beans	0.00075 lb ai/lb seed	281,250 lb seed	9.1	0.16	0.024	4,000	0.00042	2,500	27
	Soybean	0.00075 lb ai/lb seed	281,250 lb seed	9.1	0.16	0.024	4,000	0.00042	2,500	27
	Succulent Peas and Beans	0.00075 lb ai/lb seed	339,500 lb seed	9.1	0.16	0.029	3,300	0.00051	2,100	22
	Head and Stem Brassica	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	380,000	0.0000045	230,000	2,500
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	380,000	0.0000045	230,000	2,500
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	380,000	0.0000045	230,000	2,500
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	380,000	0.0000045	230,000	2,500
	Fruiting Vegetables (eggplant, bell and non-bell pepper, groundcherry, pepino, tomato, tomatillo)	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	380,000	0.0000045	230,000	2,500
Multiple Activities for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	125,000 lb seed	42 (gloves)	1.6	0.049	2,000	0.0019	560	9.7
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	42 (gloves)	1.6	0.049	2,000	0.0019	560	9.7
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	42 (gloves)	1.6	0.13	720	0.0051	210	3.5
	Dried Peas and Beans	0.00075 lb ai/lb seed	281,250 lb seed	42 (gloves)	1.6	0.11	870	0.0042	250	4.3
	Soybean	0.00075 lb ai/lb seed	281,250 lb seed	42 (gloves)	1.6	0.11	870	0.0042	250	4.3
	Succulent Peas and Beans	0.00075 lb ai/lb seed	339,500 lb seed	42 (gloves)	1.6	0.13	720	0.0051	210	3.5
	Head and Stem Brassica	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	82,000	0.000045	23,000	400
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	82,000	0.000045	23,000	400
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	82,000	0.000045	23,000	400
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	82,000	0.000045	23,000	400
	Fruiting Vegetables (eggplant, bell and non-bell pepper,	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	82,000	0.000045	23,000	400

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).										
Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
	groundcherry, pepino, tomato, tomatillo)									
Planters for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	524.26 lb seed	250 (gloves)	3.4	0.0012	78,000	0.000017	63,000	570
	Cotton	0.00075 lb ai/lb seed	3,778 lb seed	250 (gloves)	3.4	0.0089	11,000	0.00012	8,800	80
	Corn (field)	0.00075 lb ai/lb seed	5,915 lb seed	250 (gloves)	3.4	0.014	6,900	0.00019	5,600	50
	Corn (pop)	0.00075 lb ai/lb seed	4,409 lb seed	250 (gloves)	3.4	0.010	9,300	0.00014	7,500	68
	Corn (sweet)	0.00075 lb ai/lb seed	6,638 lb seed	250 (gloves)	3.4	0.016	6,200	0.00021	5,000	45
	Dried Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed	250 (gloves)	3.4	0.061	1,600	0.00083	1,300	12
	Soybean	0.00075 lb ai/lb seed	33,333 lb seed	250 (gloves)	3.4	0.078	1,200	0.0011	990	8.8
	Succulent Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed	250 (gloves)	3.4	0.061	1,600	0.00083	1,300	12
	Head and Stem Brassica	0.00075 lb ai/lb seed	211 lb seed	250 (gloves)	3.4	0.00049	190,000	0.0000067	160,000	1400
	Cucurbits	0.00075 lb ai/lb seed	929 lb seed	250 (gloves)	3.4	0.0022	44,000	0.000030	35,000	320
	Lettuce, head	0.00075 lb ai/lb seed	78.41 lb seed	250 (gloves)	3.4	0.00018	520,000	0.0000025	420,000	3,800
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	63 lb seed	250 (gloves)	3.4	0.00015	650,000	0.0000020	530,000	4,800
	Fruiting Vegetables - Tomato	0.00075 lb ai/lb seed	87 lb seed	250 (gloves)	3.4	0.000204	470,000	0.0000028	380,000	3,400
	Fruiting Vegetables - Eggplant	0.00075 lb ai/lb seed	605 lb seed	250 (gloves)	3.4	0.0014	68,000	0.000019	54,000	490
	Fruiting Vegetables -Bell pepper	0.00075 lb ai/lb seed	112 lb seed	250 (gloves)	3.4	0.00026	370,000	0.0000036	300,000	2,700
	Fruiting Vegetables -Non Bell pepper	0.00075 lb ai/lb seed	334 lb seed	250 (gloves)	3.4	0.00078	120,000	0.000011	98,000	880
On Farm Hopper/Planter Box Loader/Applicator for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	524.26 lb seed	220	1.2	0.0011	89,000	0.0000011	970,000	870
	Cotton	0.00075 lb ai/lb seed	3,778 lb seed			0.0078	12,000	0.0000078	140,000	120
	Corn (field)	0.00075 lb ai/lb seed	5,915 lb seed			0.012	7,900	0.000012	86,000	77
	Corn (pop)	0.00075 lb ai/lb seed	4,409 lb seed			0.0091	11,000	0.0000091	120,000	110
	Corn (sweet)	0.00075 lb ai/lb seed	6,638 lb seed			0.014	7,000	0.000014	77,000	68
	Dried Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed			0.054	1,800	0.000054	20,000	18

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline or (PPE)		Dermal		Inhalation		Total
				Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
	Soybean	0.00075 lb ai/lb seed	33,333 lb seed			0.069	1,400	0.000069	15,000	14
	Succulent Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed			0.054	1,800	0.000054	20,000	18
	Head and Stem Brassica	0.00075 lb ai/lb seed	211 lb seed			0.00044	220,000	0.00000043	2,400,000	2,100
	Cucurbits	0.00075 lb ai/lb seed	929 lb seed			0.0019	50,000	0.0000019	550,000	490
	Lettuce, head	0.00075 lb ai/lb seed	78.41 lb seed			0.00016	600,000	0.00000016	6,500,000	5,800
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	63 lb seed			0.00013	750,000	0.00000013	8,100,000	7,300
	Fruiting Vegetables - Tomato	0.00075 lb ai/lb seed	87 lb seed			0.00018	540,000	0.00000018	5,900,000	5,300
	Fruiting Vegetables - Eggplant	0.00075 lb ai/lb seed	605 lb seed			0.0013	77,000	0.0000012	850,000	750
	Fruiting Vegetables -Bell pepper	0.00075 lb ai/lb seed	112 lb seed			0.00023	420,000	0.00000023	4,600,000	4,100
	Fruiting Vegetables -Non Bell pepper	0.00075 lb ai/lb seed	334 lb seed			0.00069	140,000	0.00000069	1,500,000	1,400

1 Assessment based on maximum registered or proposed new use bifenthrin application rate for each scenario. Crops were grouped according to application rates and applicable exposure scenarios to cover all uses.

2 Based on ExpoSAC Policy 9.1. For seed treatment, HED default for lb seed treated/planted per day from HED Exposure Science Advisory Council Interim Policy 15.1 and the BEAD memo "Acres Planted Per Day and Seeding Rates of Crops Grown in the United States" (J. Becker, March 2011).

3 Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data). Level of mitigation: Baseline unless shown otherwise. DL= double layer, EC = engineering control. Unit Exposures for seed treatment from HED Exposure Science Advisory Council Policy 14: Standard Operating Procedures for Seed Treatment (baseline inhalation = no respirator).

4 Dose = Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/ gal or lb ai/A) × Area Treated or Amount Handled Daily (gal/day, lb seed, or A/day) ÷ BW (80 kg).

5 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day), where dermal POD = 96.3 mg/kg/day and inhalation POD = 1.05 mg/kg/day. Bold MOEs represent estimates of concern (LOC = 100 for dermal, 30 for inhalation).

6 ARI = Aggregate Risk Index = 1÷ [(Dermal LOC ÷ Dermal MOE) + (Inhalation LOC ÷ Inhalation MOE)]. ARIs greater than 1 are not of concern.

Table D.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Non-Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Application Type	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline		Dermal		Inhalation		Total
					Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
Mixer/Loader											
Mixing/Loading Granules for Tractor-Drawn Spreader Applications	Broadcast	Golf course (fairways, tees, greens)	0.4 lb ai/acre	40 acres	8.4	1.7	0.0017	5,7000	0.00034	3,100	87
		Golf course (tees and greens only)	0.4 lb ai/acre	5 acres	8.4	1.7	0.00021	460,000	0.000043	25,000	710
Mixing/Loading Liquids for Impregnation	On-farm treatment	Fertilizer, dry bulk, impregnated	0.23 lb ai/acre	160 acres	220	0.219	0.101	950	0.000101	10,000	9.2
Mixing/Loading Liquids for Injector	Tree Injection	Wood treatment to in-service poles, posts, and other timber members	0.0052 lb ai/gallon	5 gallons	220	0.219	0.000072	1,300,000	0.000000071	15,000,000	13,000
Mixing/Loading Liquids for Groundboom	Broadcast	Golf course (tees and greens only)	0.2 lb ai/acre	5 acres	220	0.219	0.0028	35,000	0.0000027	380,000	340
		Golf course (fairways, tees, greens)	0.2 lb ai/acre	40 acres	220	0.219	0.022	4,400	0.000022	48,000	43
Applicator											
Applying Sprays with Groundboom Application Equipment	Broadcast	Golf course (tees and greens only)	0.2 lb ai/acre	5 acres	78.6	0.34	0.00098	98,000	0.0000043	250,000	880
		Golf course (fairways, tees, greens)	0.2 lb ai/acre	40 acres	78.6	0.34	0.0079	12,000	0.000034	31,000	110

Table D.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Non-Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Application Type	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline		Dermal		Inhalation		Total
					Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
Applying Fertilizer, dry bulk, impregnated Tractor-drawn Spreader	On-farm treatment	Field crop, typical	0.23 lb ai/acre	160 acres	9.9	1.2	0.0046	21,000	0.00055	1,900	49
		Field crop, high-acreage	0.23 lb ai/acre	160 acres	9.9	1.2	0.0046	21,000	0.00055	1,900	49
Applying Granules with a Tractor-Drawn Spreader	Broadcast	Golf course (fairways, tees, greens)	0.4 lb ai/acre	40 acres	9.9	1.2	0.0020	49,000	0.00024	4,400	110
		Golf course (tees and greens only)	0.4 lb ai/acre	5 acres	9.9	1.2	0.00025	390,000	0.000030	35,000	900
Applying RTU (PL) Aerosol can	Crack and Crevice	Warehouse	0.00075 lb ai/can	10 cans	190000	1300	0.018	5,400	0.00012	8,600	45
		Residential Living Spaces (homes, apartments)	0.00075 lb ai/can	10 cans	190000	1300	0.018	5,400	0.00012	8,600	45
		Childcare center/schools/institutions	0.00075 lb ai/can	10 cans	190000	1300	0.018	5,400	0.00012	8,600	45
Mixer/Loader/Applicator											
Mixing/Loading/ Applying Liquid Formulations with Backpack Sprayer	Broadcast	Landscaping, trees/shrubs/bushes	0.0052 lb ai/gallon	40 gallons	58400	69.1	0.15	640	0.00018	5,800	6.2
		Landscaping, plants/flowers	0.0052 lb ai/gallon	40 gallons	58400	69.1	0.15	640	0.00018	5,800	6.2
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.0052 lb ai/gallon	40 gallons	58400	69.1	0.15	640	0.00018	5,800	6.2
Mixing/Loading/ Applying Liquid Formulations with Backpack	Spot	Landscaping, turf (lawns, athletic fields, parks, etc.)	0.0052 lb ai/gallon	40 gallons	8260	2.58	0.022	4,500	0.0000067	160,000	45
	Broadcast	Foundations/ perimeter	0.0052 lb ai/gallon	40 gallons	8260	2.58	0.022	4,500	0.0000067	160,000	45
		Structural (termiticide)	0.0104 lb ai/gallon	40 gallons	2510	30	0.013	7,400	0.00016	6,700	56

Table D.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Non-Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Application Type	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline		Dermal		Inhalation		Total
					Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0106 lb ai/gallon	40 gallons	2510	30	0.013	7,200	0.00016	6,600	54
		Poultry/livestock house/horse barn/feed lot	0.0052 lb ai/gallon	40 gallons	2510	30	0.0065	15,000	0.000078	13,000	110
Mixing/Loading/ Applying Liquid Formulations with Manually-pressurized Handwand,	Broadcast	Landscaping, trees/shrubs/bushes	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
		Landscaping, plants/flowers	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
		Poultry/livestock house/horse barn/feed lot	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
		Foundations/ perimeter	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
		Interior landscaping	0.23 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0106 lb ai/gallon	40 gallons	100000	30	0.53	180	0.00016	6,600	1.8
	Spot	Mounds/nests	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
	Broadcast	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
	Crack and Crevice	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
		Warehouse	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3

Table D.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Non-Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Application Type	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline		Dermal		Inhalation		Total
					Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
		Residential Living Spaces (homes, apartments)	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
Mixing/Loading/ Applying Liquid Formulations with Mechanically-pressurized Handgun	Broadcast	Golf course (tees and greens only)	0.2 lb ai/acre	5 acres	1140	1.9	0.014	6,700	0.000024	44,000	64
		Golf course (fairways, tees, greens)	0.2 lb ai/acre	5 acres	1140	1.9	0.014	6,700	0.000024	44,000	64
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.23 lb ai/acre	5 acres	1140	1.9	0.016	5,900	0.000027	38,000	56
		Landscaping, trees/shrubs/bushes	0.0052 lb ai/gallon	1000 gallons	6050	8.68	0.39	240	0.00056	1,900	2.3
		Structural (termiticide)	0.0104 lb ai/gallon	1000 gallons	1800	79	0.23	410	0.0103	100	1.8
		Warehouse	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	820	0.0051	200	3.7
		Poultry/livestock house/horse barn/feed lot	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	820	0.0051	200	3.7
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0106 lb ai/gallon	1000 gallons	1800	79	0.24	400	0.011	100	1.8
Mixing/Loading/ Applying Liquid Formulations with Injector	Broadcast	Structural (termiticide)	0.0104 lb ai/gallon	1000 gallons	1300	2.2	0.17	570	0.00029	3,700	5.4
Mixing/Loading/ Applying WSP Formulations with Backpack	Broadcast	Structural (e.g., bridges, shipyards, home decks, foundations)	0.0052 lb ai/gallon	40 gallons	2510	30	0.0065	15,000	0.000078	13,000	110
		Structural (termiticide)	0.0052 lb ai/gallon	40 gallons	2510	30	0.0065	15,000	0.000078	13,000	110

Table D.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Non-Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Application Type	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline		Dermal		Inhalation		Total
					Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
		Foundations/perimeter	0.0052 lb ai/gallon	40 gallons	8260	2.58	0.022	4,500	0.0000067	160,000	45
Mixing/Loading/ Applying WSP Formulations with Manually-pressurized Handwand	Broadcast	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
	Crack and Crevice	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
		Warehouse	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
		Residential Living Spaces (homes, apartments)	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
		Childcare center/schools/institutions	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	1,300	0.0029	370	6.3
	Broadcast	Foundations/ perimeter	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
	Spot	Mounds/nests	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	370	0.000078	13,000	3.7
Mixing/Loading/ Applying WSP Formulations with Mechanically-pressurized Handgun	Broadcast	Structural (termiticide)	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	820	0.0051	200	3.7
		Warehouse	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	820	0.0051	200	3.7
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	820	0.0051	200	3.7
Loading/Applying Granule Formulations with a Belly grinder	Broadcast	Landscaping, trees/shrubs/bushes	0.2 lb ai/acre	1 acres	10000	62	0.025	3,900	0.00016	6,800	33
		Landscaping, plants/flowers	0.2 lb ai/acre	1 acres	10000	62	0.025	3,900	0.00016	6,800	33

Table D.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Non-Agricultural Uses of Bifenthrin (Registered and Proposed Uses).

Exposure Scenario	Application Type	Crop / Target Category	Maximum Application Rate[1]	Amount Handled / Area Treated[2]	Unit Exposures [3] (ug/lb ai) Baseline		Dermal		Inhalation		Total
					Dermal	Inhalation	Dose [4] (mg/kg-day)	MOE[5]	Dose[4] (mg/kg-day)	MOE[5]	ARI[6]
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.4 lb ai/acre	1 acres	10000	62	0.05	1,900	0.00031	3,400	16
Loading/Applying Granule Formulations with a Rotary Spreader	Broadcast	Golf course (tees and greens only)	0.4 lb ai/acre	5 acres	440	10	0.011	8,800	0.00025	4,200	54
		Golf course (fairways, tees, greens)	0.4 lb ai/acre	5 acres	440	10	0.011	8,800	0.00025	4,200	54
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.4 lb ai/acre	5 acres	440	10	0.011	8,800	0.00025	4,200	54
Loading/Applying Liquid Formulations with Brush/roller	Broadcast	Wood treatment	0.00428 lb ai/gallon	5 gallons	180000	280	0.048	2,000	0.000075	14,000	19

1 Assessment based on maximum registered or proposed new use bifenthrin application rate for each scenario.
2 Based on ExpoSAC Policy 9.1.
3 Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data).
4 Dose = Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/ gal or lb ai/A) × Area Treated or Amount Handled Daily (gal/day or A/day) ÷ BW (80 kg).
5 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day), where dermal POD = 96.3 mg/kg/day and inhalation POD = 1.05 mg/kg/day. Bold MOEs represent estimates of concern (LOC = 100 for dermal, 30 for inhalation).
6 ARI = Aggregate Risk Index = 1÷ [(Dermal LOC ÷ Dermal MOE) + (Inhalation LOC ÷ Inhalation MOE)]. ARIs greater than 1 are not of concern to the Agency.

Table D.3. Occupational Post-Application Non-Cancer Dermal Exposure and Risk Estimates for Bifenthrin.

Policy Crop Group Category	Crops	Application Rate[1] (lb ai/A)	Maximum Transfer Coefficient[2] (cm^2/hr)	Activities for Maximum TC	DAT (Day After Treatment)	DFR Residue[3] (ug/cm^2)	Dose[4] (mg/kg-day)	MOE[5]
Berry, low	Blueberry, lowbush	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Cranberry	0.1	1100	Hand harvesting (raking), scouting	0	0.27	0.030	3,300
	Strawberry	0.2	1100	Hand harvesting	0	0.54	0.059	1,600
Bunch/bundle	Hop	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Tobacco	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Field / row crop, low / medium	Alfalfa	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Canola, Crambe, Rapeseed	0.04	1100	Scouting	0	0.11	0.012	8,200
	Cotton	0.1	5050	Harvesting, Mechanical, Tramper	0	0.20	0.101	950
	Grass (forage, fodder and hay, grass grown for seed), Pasture and Rangeland	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Meadowfoam (grown for seed)	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Peanut	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Soybean	0.1	1100	Scouting	0	0.27	0.030	3,300
	Succulent Peas and Beans, Dried Peas and Beans	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Field / row crop, tall	Corn, field	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Corn, pop	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Corn, sweet, grain	0.1	8800	Detasseling, Hand; Harvesting, Hand	0	0.27	0.236	410
	Corn, sweet, processing	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Tree, "fruit", deciduous	Nectarine	0.2	3600	Thinning Fruit	0	0.54	0.193	500
	Peach	0.2	3600	Thinning Fruit	0	0.54	0.193	500
	Pome Fruit (Pear, Apple)	0.2	3600	Thinning Fruit	0	0.54	0.193	500
	Pomegranate	0.2	1400	Harvesting, Hand	0	0.54	0.075	1,300

Table D.3. Occupational Post-Application Non-Cancer Dermal Exposure and Risk Estimates for Bifenthrin.

Policy Crop Group Category	Crops	Application Rate[1] (lb ai/A)	Maximum Transfer Coefficient[2] (cm^2/hr)	Activities for Maximum TC	DAT (Day After Treatment)	DFR Residue[3] (ug/cm^2)	Dose[4] (mg/kg-day)	MOE[5]
Tree, "fruit", evergreen	Avocado	0.075	1400	Harvesting, Hand	0	0.20	0.028	3,400
	Christmas tree	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Tree, "nut"	Tree Nut - Almond	0.2	580	Scouting	0	0.54	0.031	3,100
	Tree Nut - Hazelnut	0.2	580	Scouting	0	0.54	0.031	3,100
	Tree Nut - Macadamia nut	0.2	580	Pruning, Hand; Scouting	0	0.54	0.031	3,100
	Tree Nut - Pecan	0.2	580	Pruning, Hand; Scouting	0	0.54	0.031	3,100
	Tree Nut - Pistachio	0.2	1400	Harvesting, Hand (net)	0	0.54	0.075	1,300
	Tree Nut - Walnut, English	0.2	580	Scouting	0	0.54	0.031	3,100
Turf / sod	Golf Course	0.4 (granular)	3700	Maintenance	0	0.122	0.045	2,100
	Sod	0.21	6700	Maintenance; Harvesting, Slab; Transplanting/Planting	0	0.064	0.043	2,300
Unassigned	Nursery Crop (Ornamentals, Non-bearing Plants)	0.125	1900	Irrigation (hand set)	0	0.34	0.064	1,500
	Greenhouse Crop (Ornamentals, Non-bearing Plants)	0.00125 lb ai/gal	230	Harvesting, hand; Pruning, hand; Scouting; Container moving; Weeding, hand; Transplanting; Grafting; Propagating; Pruning, hand; Transplanting; Pinching, Tying/Training	0	0.36	0.0083	12,000
Vegetable, "root"	Tuberous and Corm Vegetables - Carrot	0.3	1900	Irrigation (hand set)	0	0.80	0.153	630
	Tuberous and Corm Vegetables - Potato	0.3	1900	Irrigation (hand set)	0	0.80	0.153	630

Table D.3. Occupational Post-Application Non-Cancer Dermal Exposure and Risk Estimates for Bifenthrin.								
Policy Crop Group Category	**Crops**	**Application Rate[1] (lb ai/A)**	**Maximum Transfer Coefficient[2] (cm^2/hr)**	**Activities for Maximum TC**	**DAT (Day After Treatment)**	**DFR Residue[3] (ug/cm^2)**	**Dose[4] (mg/kg-day)**	**MOE[5]**
Vegetable, cucurbit	Cucurbits - Cantaloupe, Cucumber, Gourd, Pumpkin, Summer Squash, Winter Squash, Watermelon	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Vegetable, Fruiting	Fruiting Vegetables - Eggplant, Bell Pepper, Chili Pepper, Tomato, Tomato Processing	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Okra	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Vegetable, head and stem Brassica	Head and Stem Brassica - Broccoli	0.1	4200	Scouting; Harvesting, Hand; Weeding, Hand	0	0.27	0.113	850
	Head and Stem Brassica - Brussels Sprouts	0.1	4200	Scouting; Harvesting, Hand; Weeding, Hand; Topping	0	0.27	0.113	850
	Head and Stem Brassica - Cabbage	0.1	4200	Weeding, Hand	0	0.27	0.113	850
	Head and Stem Brassica - Cauliflower	0.1	4200	Scouting; Harvesting, Hand; Tying/Training; Weeding, Hand	0	0.27	0.113	850
Vegetable, leafy	Cilantro, Coriander	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Head and Stem Brassica - Cabbage, chinese, Napa	0.1	4200	Weeding, Hand	0	0.27	0.113	850
	Leafy Brassicas - Cabbage, chinese, Bok choy	0.1	4200	Weeding, Hand	0	0.27	0.113	850
	Leafy Brassicas, Turnip Greens - Collards, Kale,	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900

Table D.3. Occupational Post-Application Non-Cancer Dermal Exposure and Risk Estimates for Bifenthrin.								
Policy Crop Group Category	**Crops**	**Application Rate[1] (lb ai/A)**	**Maximum Transfer Coefficient[2] (cm^2/hr)**	**Activities for Maximum TC**	**DAT (Day After Treatment)**	**DFR Residue[3] (ug/cm^2)**	**Dose[4] (mg/kg-day)**	**MOE[5]**
	Mustard Green, Watercress							
	Leafy Petiole Vegetables - Celery	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Spinach	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Vegetable, leafy, except Brassica	Greens, Leafy	0.1	1100	Hand Harvesting	0	0.27	0.030	3,300
	Parsley	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Spinach	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Vegetable, stem / stalk	Artichoke	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
Vine / trellis	Bushberry	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Caneberry	0.1	1900	Irrigation (hand set)	0	0.27	0.051	1,900
	Grape, wine	0.1	10100	Tying/Training; Harvesting, Hand; Leaf Pulling	0	0.27	0.271	360
	Grape, juice	0.1	10100	Tying/Training; Harvesting, Hand; Leaf Pulling	0	0.27	0.271	360
	Grape, table	0.1	19300	Girdling, Turning	0	0.27	0.518	190
	Grape, raisin	0.1	5500	Tying/Training; Harvesting, Hand; Leaf Pulling	0	0.280	0.148	650

1 Application rates are the maximum application rates determined from EPA registered labels for bifenthrin.
2 Transfer Coefficient and Post Application Activities from EPA's Occupational Pesticide Re-entry Exposure Calculator – Revised January 2017.
3 DFR/TTR Data sources:
Greenhouse ornamentals: MRID 44955201 (chrysanthemums): Day 0 concentration = 0.574 ug/cm^2; Study application rate = 0.002 lb ai/gallon
Sod/Turf: MRID 44955201 (turf): Day 0 concentration = 0.0624 ug/cm^2; Study application rate = 0.2 lb ai/A
Other crops: MRID 44684401 (strawberries): Day 0 concentration = 0.537 ug/cm^2; Study application rate = 0.2 lb ai/A
4 Daily Dermal Dose = [DFR (µg/cm^2) × Transfer Coefficient × 0.001 mg/µg × 8 hrs/day] ÷ BW (80 kg).
5 MOE = POD (96.3 mg/kg/day) / Daily Dermal Dose, LOC = 100.

Appendix E. International Residue Limit Status Sheet (128825, 07/13/2016).

Summary of US and International Tolerances and Maximum Residue Limits				
***Residue Definition*:**				
US		**Canada**	**Mexico[1]**	**Codex[2]**
§ 180.442 (a) General. Bifenthrin, (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate		(2-methyl[1,1'-biphenyl]-3-yl)methyl (1R,3R)-rel-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate		Bifenthrin (sum of isomers). The residue is fat-soluble.
Commodity	***Tolerance (ppm) /Maximum Residue Limit (mg/kg)***			
	US	**Canada**	**Mexico[1]**	**Codex[2]**
Apple, wet pomace	1.5			
Avocado	0.50			
Almond, hulls	2.0			
Artichoke, globe	1.0			
Banana[3]	0.10			0.1
Beet, garden, roots	0.45	0.5		
Beet, garden, tops	15			
Berry, low growing, subgroup 13-07G	3.0			1 strawberry (proposed)[6]
Brassica, head and stem, subgroup 5A, except cabbage	0.6	0.9		0.4 (Brassica (cole or cabbage)
Brassica, leafy greens, subgroup 4-16B	15	4		4 mustard greens
Bushberry subgroup 13-07B	1.8			
Cabbage	4.0	7		
Caneberry subgroup 13-07A	1.0	1		1 dewberries (including boysenberry and loganberry), raspberries (black and red)
Cattle, fat	1.0	0.1		
Cattle, meat byproducts	0.10	0.05		0.2
Cattle, meat	0.50	0.05		3
Coriander, dried leaves	25			
Coriander, leaves	6.0			
Coriander, seed	5.0			
Corn, field, forage	3.0			
Corn, field, grain	0.05			0.05 (*)
Corn, field, stover	5.0			15 maize fodder (dry)
Corn, pop, grain	0.05			
Corn, pop, stover	5.0			
Corn, sweet, forage	3.0			
Corn, sweet, kernel plus cob with husk removed	0.05			
Corn, sweet, stover	5.0			
Cotton, undelinted seed	0.50			0.5
Eggplant	0.05	0.5		0.3
Egg	0.05	0.01		
Fruit, citrus, group 10-10	0.05			0.05
Fruit, pome, group 11-10, except mayhaw	0.70	0.9 pears		

Summary of US and International Tolerances and Maximum Residue Limits				
***Residue Definition*:**				
US		**Canada**	**Mexico[1]**	**Codex[2]**
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.20			
Goat, fat	1.0	0.1		
Goat, meat byproducts	0.10	0.05		0.2
Goat, meat	0.50	0.05		3 (fat)
Grain, aspirated fractions	70			
Groundcherry	0.50	0.5		
Herb subgroup 19A	0.05			
Hog, fat	1.0	0.1		
Hog, meat byproducts	0.10	0.05		0.2
Hog, meat	0.50	0.05		3 (fat)
Hop, dried cones	10.0			20
Horse, fat	1.0	0.1		
Horse, meat byproducts	0.10	0.05		0.2
Horse, meat	0.50	0.05		3 (fat)
Leafy petioles subgroup 4B	3.0	3		
Lettuce, head	3.0	4		
Mayhaw	1.4	1.5		
Milk, fat (reflecting 0.1 ppm in whole milk)	1.0	0.02		3 0.2 milks
Nut, tree, group 14-12	0.05			0.05
Okra	0.50	0.5		0.2 (proposed)[5]
Pea and bean, dry shelled, except soybean, subgroup 6C	0.15	0.15		0.3
Pea and bean, succulent shelled, subgroup 6B	0.05	0.05		
Peach, subgroup 12-12B	0.70			
Peanut	0.05			
Pepino	0.50	0.5		
Pepper, bell	0.50	0.5		0.5 peppers 5 peppers chili dried
Pepper, nonbell	0.50	0.5		
Pepper/eggplant subgroup 8-10B		0.5		
Pomegranate	0.50			
Poultry, fat	0.05	0.05		
Poultry, meat byproducts	0.05	0.05		
Poultry, meat	0.05	0.02		
Radish, tops	4.5			4
Rapeseed, seed	0.05			0.05 0.1 rapeseed oil, edible
Sheep, fat	1.0	0.1		
Sheep, meat byproducts	0.10	0.05		0.2
Sheep, meat	0.50	0.05		3
Soybean, hulls	0.50			
Soybean, refined oil	0.30			
Soybean, seed	0.20	0.2		0.3 pulses
Spinach	0.20	0.3		
Tea, dried[3]	30	30		30
Tomato subgroup 8-10A	0.15	0.5		0.3
Vegetable, cucurbit, group 9	0.40	0.5		

Summary of US and International Tolerances and Maximum Residue Limits				
***Residue Definition*:**				
US		**Canada**	**Mexico[1]**	**Codex[2]**
Vegetable, legume, edible podded, subgroup 6A	0.60	0.8		
Vegetable, root, subgroup 1B except sugar beet and garden beet	0.10	0.05 carrot, beet garden		0.05 root and tuber vegetables
Vegetable, tuberous and corm, subgroup 1C	0.05	0.05		0.05
MRLs with no US Equivalent				
Barley				0.05 (*) (proposed)[4]
Barley straw and fodder, dry				0.5 (proposed)[4]
Mango				0.5 (proposed)[5]
Okra				0.2 (proposed)[5]
Papaya				0.4 (proposed)[5]
Pea hay or pea fodder (dry)				0.7
Spices, fruits and berries				0.03
Spices, roots and rhizomes				0.05
Wheat				0.5 Po
Wheat bran, unprocessed				2 PoP
Wheat germ				1 Po
Leaf Petioles Vegetables (crop subgroup 22B)		3		
Completed: M. Negussie; 11/22/2016				

[1] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.
[2] * = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat. (fat) = to be measured on the fat portion of the sample. MRLs indicated as proposed have not been finalized by the CCPR and the CAC.
[3] There are no US registrations.
[4] CCPR retained the existing CXLs for barley and barley straw and fodder, dry, awaiting the outcome of the 2018 JMPR.
[5] CCPR retained the draft MRLs for mango; okra and papaya at Step 7, awaiting the2017 JMPR review of new data submitted by Kenya.
[6] CCPR retained the draft MRL for strawberry, celery and lettuce head at step 4 (in light of acute intake risk identified by the 2015 JMPR) and await an alternative GAP for review by the 2017 JMPR.

Summary of US and International Tolerances and Maximum Residue Limits				
***Residue Definition*:**				
US		**Canada**	**Mexico[1]**	**Codex[2]**
§ 180.442 (c) Tolerances with regional registrations. Bifenthrin, (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate		(2-methyl[1,1'-biphenyl]-3-yl)methyl (1R,3R)-rel-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate		Bifenthrin (sum of isomers). The residue is fat-soluble.
Commodity	***Tolerance (ppm) /Maximum Residue Limit (mg/kg)***			
	US	**Canada**	**Mexico[1]**	**Codex[2]**
Grass, forage	4.0			
Grass, hay	15			
Completed: M. Negussie; 11/22/2016				

Appendix F. Pesticide Use Pattern

Table F.1. Summary of Directions for Agricultural Occupational Uses of Bifenthrin (Proposed Uses).

Use Site	Formulation	Application Equipment	Application Rate	PHI (days)	RTI (days)	EPA Registration No. (% ai)
Avocado	Liquid	Ground, Aerial, Airblast, Chemigation, Handheld	0.075 lb ai/A or 0.001 lb ai/gal	1	5-14	279-3315 (11.25% ai) 379-3329 (9.72 % ai)
Citrus Group 10-10	WP in WSB[1]	Ground, Handheld	0.5 lb ai/A or 0.0125 lb ai/gal	1	--	279-3108 (10 % ai)
	Liquid	Ground, Handheld	0.5 lb ai/A or 0.0125 lb ai/gal	1	--	279-3313 (25.1 % ai)
Peach Subgroup 12-12B	WP in WSB[1]	Ground, Airblast, Aerial, Chemigation, Handheld	0.2 lb ai/A or 0.004 lb ai/gal	14	30	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Airblast, Chemigation, Handheld	0.2 lb ai/A or 0.004 lb ai/gal	14	30	279-3313 (25.1 % ai)
Pome Fruit Group 11-10	WP in WSB[1]	Ground (specified) Airblast, Aerial, Chemigation, Handheld	0.2 lb ai/A or 0.004 lb ai/gal	14	30	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Airblast, Chemigation, Handheld	0.2 lb ai/A or 0.004 lb ai/gal	14	30	279-3313 (25.1 % ai)
Pomegranate	WP in WSB[1]	Ground, Aerial, Airblast, Chemigation, Handheld	0.2 lb ai/A or 0.004 lb ai/gal	14	14	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Airblast, Chemigation, Handheld	0.2 lb ai/A or 0.004 lb ai/gal	14	14	279-3313 (25.1 % ai)
Tree Nut Group 14-12	WP in WSB[1]	Ground, Airblast, Aerial, Chemigation, Handheld	0.2 or 0.004 lb ai/gal	7 to 21	--	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Airblast, Chemigation, Handheld	0.2 or 0.004 lb ai/gal	7 to 21	--	279-3313 (25.1 % ai)
Caneberries Subgroup 13-07A	WP in WSB[1]	Ground, Aerial, Airblast, Chemigation, Handheld	0.1 or 0.002 lb ai/gal	3	one pre-bloom, one post-bloom	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Airblast, Chemigation, Handheld	0.1 lb ai/A or 0.002 lb ai/gal	3	one pre-bloom, one post-bloom	279-3313 (25.1 % ai)
Small Fruit Vine Climbing Subgroup 13-07F (except fuzzy kiwifruit)	WP in WSB[1]	Ground, Aerial, Airblast, Chemigation, Handheld	0.1 lb ai/A or 0.004 lb ai/gal	30	--	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Chemigation, Airblast, Handheld	0.1 lb ai/A or 0.004 lb ai/gal	30	--	279-3313 (25.1 % ai)

Table F.1. Summary of Directions for Agricultural Occupational Uses of Bifenthrin (Proposed Uses).						
Use Site	**Formulation**	**Application Equipment**	**Application Rate**	**PHI (days)**	**RTI (days)**	**EPA Registration No. (% ai)**
Brassica Leafy Subgroup 14-16B	WP in WSB[1]	Ground, Aerial, Airblast, Chemigation, Handheld	0.1 lb ai/A or 0.01 lb ai/gal	7	7	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Chemigation, Handheld	0.1 lb ai/A or 0.01 lb ai/gal	1	--	279-3313 (25.1 % ai)
Low-Growing Berries Subgroup 13-07G (except cranberry)	WP in WSB[1]	Ground, Aerial, Airblast, Chemigation, Handheld	0.2 lb ai/A	0	7-14	279-3108 (10 % ai)
Cranberry	WP in WSB[1]	Ground, Aerial, Airblast, Chemigation, Handheld	0.1 lb ai/A or 0.0042 lb ai/gal	30	7	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Chemigation, Handheld	0.1 lb ai/A or 0.0042 lb ai/gal	30	7	66222-99 (25.1% ai) 66222-261 (24% ai)
Pepper/Eggplant Subgroup 8-10B	WP in WSB[1]	Ground, Aerial, Chemigation, Handheld	0.1 lb ai/A or 0.01 lb ai/gal	7	7	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Chemigation, Handheld	0.1 lb ai/A or 0.01 lb ai/gal	7	7	279-3313 (25.1 % ai)
Tomato Subgroup 8-10A	WP in WSB[1]	Ground, Aerial, Chemigation, Handheld	0.08 lb ai/A or 0.0053 lb ai/gal	1	10	279-3108 (10 % ai)
	Liquid	Ground, Aerial, Chemigation, Handheld	0.1 lb ai/A or 0.01 lb ai/gal	1	10	279-3313 (25.1 % ai)

1 WSB = water soluble bag.

Table. F.2. Summary of Directions for Residential Handler Uses of Bifenthrin (Existing Uses).						
Use Site	**Formulation**	**Application Type**	**Application Equipment**	**Application Timing**	**Maximum Application Rate**	**Representative Label**
Indoor Environment Uses						
Indoor surfaces/voids (including hard floors and carpets, not for use on mattresses)	Dust	Perimeter, Crack and Crevice, Void, and/or Spot	Hand duster, from a shaker can, or with a paintbrush	When needed	0.0000009 lb ai/ ft^2	1021-1858[1]
	RTU Aerosol		Aerosol can	When needed	0.05% ai [16 oz can] or 0.0005 lb ai/16 oz-can	239-2697
			Aerosol can with injector tip	When needed	0.06% ai [20 oz can] or 0.00075 lb ai/can	279-9549
	RTU Liquid		Pull Type Sprayer	When Needed	0.025 lb ai/gal	53883-228
	Liquid Concentrate		Pump-up sprayer	When needed	0.004l lb ai/gal	53883-228
Outdoor Environment Uses						
Outdoor surfaces/voids: Around Home Foundations, Outdoor Impervious Surfaces, Wood Piles/Structures, and/or Fence Posts	Dust	Perimeter, Crack and Crevice, Void, and/or Spot	Hand duster, from the shaker can, or with a paintbrush	When needed	0.000005 lb ai/ft^2	1021-1858
	Granular		Drop, rotary, and hand-held spreaders	When needed	0.0000048 lb ai/ft^2 covered	228-494
	RTU Aerosol		Aerosol can	When needed	0.05% ai [16 oz can] or 0.0005 lb ai/can	239-2697

Table. F.2. Summary of Directions for Residential Handler Uses of Bifenthrin (Existing Uses).

Use Site	Formulation	Application Type	Application Equipment	Application Timing	Maximum Application Rate	Representative Label
			Aerosol can with injector tip	When needed	0.06% ai [20 oz can] or 0.00075 lb ai/16-oz-can	279-9549
	RTU Liquid		Hose-end Sprayer	When needed	0.102 lb ai/A	53883-228
	Liquid Concentrate		Tank sprayers, sprinkler can	When needed	0.00521 lb ai/gal	279-3152
			Hose-End	When needed	0.196 lb ai/A	53883-228
Lawns	Dust[3]	Broadcast, Perimeter, Spot	Hand duster, from the shaker can, or with a paintbrush	When needed	0.02 lb ai/A or 0.0000005 lb ai/ft^2	1021-1858
	Granular		Drop, rotary, and hand-held spreaders	When needed	0.0000048 lb ai/ft^2 or 0.21 lb ai/A	228-494
	RTU Liquid		Hose-end Sprayer	When needed	0.102 lb ai/A	53883-228
	Liquid Concentrate		Tank sprayers	When needed	0.00521 lb ai/gal; 0.000052 lb ai/ft^2 or 2.3 lb ai/A	279-3152
			Hose-End	When needed	0.196 lb ai/A	53883-228
Ornamental Trees/Shrubs/Flowers and/or Garden Vegetables	Dust	Broadcast, Perimeter, Crack and Crevice, and/or Spot	Hand duster, from the shaker can, or with a paintbrush	When needed	0.02 lb ai/A or 0.0000005 lb ai/ft^2	1021-1858
	Granular		Drop, rotary, and hand-held spreaders	When needed	0.0000048 lb ai/ft^2 (0.0000024 lb ai/ft^2 for garden vegetables)	228-494
	RTU Liquid		Hose-end Sprayer	When needed	0.102 lb ai/A or 0.00117 lb ai/gal	53883-228
	Liquid Concentrate		Tank sprayers, sprinkler can	When needed	0.00521 lb ai/gal	279-3152
			Hose-End	When needed	0.196 lb ai/A 0.00000449 lb ai/ft^2	53883-228
Ant Mounds	Granular	Spot	Spoon	When needed	1 TBS per mound; 0.115% ai or 0.0000359 lb ai/mound[2]	279-3240, 228-494
	Liquid Concentrate	Drench	Sprinkler Can	When needed	0.00521 lb ai/gal; 2 gallons per mound or 0.10 lb ai/mound	279-3169
Pets (Dogs)	Ready-to-use	Shampoo	--	When needed	0.05% ai; ½ oz product (up to 7 lb dog) to 10 oz product (116-140 lb dog)	2517-139

1 Label states uses on mattresses but then later restricts uses on mattresses for bedbug use. This should be resolved during Registration Review.
2 Label did not provide information to convert the weight of tablespoons to derive a lb ai/A. Rate calculated assuming 1 TBS = 0.03125 lbs.
3 Label did not specify a rate for lawn; therefore, rate for ornamentals was used as a surrogate.

Table F.3. Summary of Directions for Agricultural Occupational Uses of Bifenthrin (Existing Uses).						
Use Site	**Formulation**	**Application Target**	**Application Type**	**Application Equipment**	**Maximum Application Rate**	**Representative Label**
Alfalfa, Clover	Liquid	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A	SLN ID-130004 (expires 12/31/2018) and UT120002 (alfalfa only, expires 04/30/2017)
Canola, Crambe	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.04 lb ai/A	279-3313; 279-3108
	Granule	Foliar	Broadcast	Ground, Air	0.04 lb ai/A	279-3244
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Cotton	Liquid, WP in WSP	Foliar	Broadcast	Air (including Ultra Low Volume (ULV) for liquid only), Ground, Chemigation	0.1 lb ai/A	279-3313; 279-3108
	Granule	Foliar	Broadcast	Ground, Air	0.1 lb ai/A	279-3244
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type treaters	0.075 lb ai/100 lb seed	279-3245
Corn, Field, Pop and Sweet	Liquid	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313
		Pre-emergence	Broadcast	Air, Ground, Chemigation	0.04 lb ai/A	279-3313
		Soil (At Plant)	Banded, In-furrow, Broadcast	Air, Ground, Chemigation	0.27 lb ai/A	279-3302
		Soil (Preplant)	Incorporation	Air, Ground, Chemigation	0.063 lb ai/A	279-3313; 279-3302
	Granule	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow, Incorporation	Air, Ground	0.1 lb ai/A	279-3244
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Dried Peas and Beans	Liquid	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Grass (forage, fodder and hay, grass grown for seed), Pasture and Rangeland	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A	279-3313; 279-3108
Peanut	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3108

Table F.3. Summary of Directions for Agricultural Occupational Uses of Bifenthrin (Existing Uses).

Use Site	Formulation	Application Target	Application Type	Application Equipment	Maximum Application Rate	Representative Label
Soybean	Liquid, WP in WSP	Foliar, Soil (At-plant, Preplant)	Broadcast, Banded, Incorporation	Air, Ground, Chemigation	0.1 lb ai/A	279-3313; 279-3302; 279-3108
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Succulent Peas and Beans	Liquid, WP in WSP	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302; 279-3108
	Granule	Foliar	Broadcast	Ground, Air	0.1 lb ai/A	279-3244
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Head and Stem Brassica	Liquid, WP in WSP	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3108; 279-3302
	Granule	Foliar	Broadcast	Ground, Air	0.1 lb ai/A	279-3244
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Cucurbits	Liquid, WP in WSP	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.005 lb ai/gal	279-3313; 279-3108, 279-3302
	Granule	Foliar	Broadcast	Ground, Air	0.1 lb ai/A	279-3244
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Lettuce, head	Liquid, WP in WSP	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.0067 lb ai/gal	279-3313; 279-3302; 279-3108
	Granule	Foliar	Broadcast	Ground, Air	0.01 lb ai/A	279-3244
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Artichoke	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.0013 lb ai/gal	279-3108; 279-3313
Spinach	Liquid, WP in WSP	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302; 279-3108
Okra	Liquid	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302
Cilantro, Coriander	Liquid	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302
Leafy Brassicas, Turnip Greens	Liquid	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302
	Flowable	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Tuberous and Corm	Liquid	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302

Table F.3. Summary of Directions for Agricultural Occupational Uses of Bifenthrin (Existing Uses).						
Use Site	**Formulation**	**Application Target**	**Application Type**	**Application Equipment**	**Maximum Application Rate**	**Representative Label**
Vegetables (i.e. Potato, Sweet potato)	Liquid	Soil (Lay-By)	Broadcast, Banded, Incorporation	Air, Ground, Chemigation, Incorporated	0.3 lb ai/A or 0.03 lb ai/gal	279-3313; 279-3302
	Liquid	Soil (At-plant)	Broadcast, Banded, In-furrow, Incorporation	Air, Ground, Chemigation, Incorporated	0.3 lb ai/A or 0.03 lb ai/gal	279-3313; 279-3302
	Granular	Soil (At-planting)	In-furrow	Ground	0.3 lb ai/A	279-3244
Tobacco	Liquid	Foliar	Broadcast	Air, Ground , Chemigation,	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302
	Liquid	Soil (pre-transplant and at-transplant)	Broadcast, Incorporation, Water treatment (at-plant)	Air, Ground, Chemigation	0.40 lb ai/A or 0.04 lb ai/gal	279-3332
Fruiting Vegetables (eggplant, bell and non-bell pepper, groundcherry, pepino, tomato, tomatillo)	Liquid, WP in WSP	Foliar, Soil (At-plant)	Broadcast, Banded, In-furrow	Air, Ground , Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302; 279-3108
	Granule (eggplant and pepper only)	Foliar	Broadcast	Ground, Air	0.1 lb ai/A	279-3244
	Flowable (eggplant and peppers only)	Seed	Commercial or On-farm	Mechanical, slurry, or mist-type	0.075 lb ai/100 lb seed	279-3245
Root Vegetables (except sugar beet)	Liquid, WP/WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.004 lb ai/gal	279-3313; 279-3108
	Granular	Soil (At-planting)	In-furrow	Ground	0.1 lb ai/A	279-3244
Mayhaw	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.0036 lb ai/gal	279-3313; 279-3108
Leafy Petiole Vegetables	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3108
Strawberries	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.21 lb ai/A or 0.0042 lb ai/A	279-3312; 279-3108
Meadowfoam (grown for seed)	Liquid	Prebloom	Broadcast	Air, Ground	0.1 lb ai/A	OR070012 (279-3313)
Bushberries	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3108
Caneberries	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.002 lb ai/gal	279-3313; 279-3108
		Drench at crown of plant	Drench	Handgun	0.1 lb ai/A or 0.0005 lb ai/gal	279-3313; 279-3108
Hops	Liquid, WP in WSP	Foliar Directed, Soil surface	Broadcast, Base of plant	Air, Ground, Chemigation	0.1 lb ai/A or 0.001 lb ai/gal	279-3108; 279-3313
Pears	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.2 lb ai/A or 0.004 lb ai/gal	279-3108; 279-3313
Citrus	Liquid, WP in WSP	Soil	Trunk to drip line spray	Backpack, Handgun, Shield sprayer	0.5 lb ai/A or 0.0125 lb ai/gal	279-3108; 279-3313

Table F.3. Summary of Directions for Agricultural Occupational Uses of Bifenthrin (Existing Uses).

Use Site	Formulation	Application Target	Application Type	Application Equipment	Maximum Application Rate	Representative Label
Grapes	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.004 lb ai/gal	279-3313; 279-3108
Tree Nuts	Liquid, WP in WSP	Foliar	Broadcast	Air, Ground, Chemigation	0.2 lb ai/A or 0.004 lb ai/A	279-3313; 279-3108
Ornamentals in Indoor and Outdoor Nurseries and Greenhouses (trees, shrubs, plants, flowers, conifers, Christmas trees, and nonbearing fruit and nut trees, and bushes)	Granular	Potting Medium	Incorporation	Incorporation	0.015 lb ai/cubic yard	70506-75
	Aerosol	Foliar/Soil	Broadcast	Total release fogger	0.005 lb ai/can [1 can/1,500 ft^2]	499-376
	Liquid	Foliar, Root	Broadcast, Drench, Dip	Ground	0.125 lb ai/A; 0.00125 lb ai/gal	279-3358
Sod Farm	Liquid	Foliar	Broadcast	Air, Ground, Chemigation	0.219 lb ai/A 0.0025 lb ai/gal	279-3313; 279-3302
		Mound	Spot (Ground Spray/Drench)	Handwand	0.00078 lb ai/gal	
	Granular	Foliar	Broadcast, Spot	Ground	0.4 lb ai/A	228-584, 279-3253
Conifer Seed Orchards	Liquid	Foliar	Broadcast	Air, Ground, Chemigation	0.2 lb ai/A or 0.002 lb ai/gal	279-3313
Christmas Tree Plantations	Liquid	Foliar	Broadcast	Air, Ground	0.1 lb ai/A or 0.005 lb ai/gal	34704-858
Trees grown for non-commercial purposes (private lands, parks, or rangeland)	Liquid	Trunk surface	Directed spray	Hydraulic sprayer (handgun)	0.6 lb ai/A	SD130002

Table F.4. Summary of Directions for Non-Agricultural Occupational Uses of Bifenthrin (Existing Uses).

Use Site	Formulation	Application Type	Application Equipment	Application Timing	Maximum Application Rate	Representative Label
Residential, institutional, public, commercial, industrial buildings (indoor surfaces/voids) [includes carpet edges, mattresses with linens removed, furniture where skin contact does not occur]	RTU Aerosol	Spot, crack and crevice	Aerosol can	When needed	0.06% ai [0.00075 lb ai per 16 oz can]	279-9549
	Liquid, WP/WSP	Spot, crack and crevice	Hand-held sprayers (backpack, tank, low pressure, coarse, coarse, pinstream); Foam sprayer; Paintbrush	When needed	5.2E-6 lb ai/ft^2 or 0.0052 lb ai/gal or 2.2 lb ai/A	70506-24; 8033-96 279-3152
Livestock/Poultry Premises, Pet Kennels	Liquid	Spot, crack and crevice	Sprayers	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24

Table F.4. Summary of Directions for Non-Agricultural Occupational Uses of Bifenthrin (Existing Uses).						
Use Site	**Formulation**	**Application Type**	**Application Equipment**	**Application Timing**	**Maximum Application Rate**	**Representative Label**
(indoor and outdoor surfaces/voids)						
Subterranean Termite (soil)	Liquid	Broadcast, Spot, Crack and crevice, Perimeter	Trenching, rodding, sub-slab injection, crack and crevice (void) injection, excavated soil treatment, spray applications; Foam	When needed	0.0104 lb ai/gal	70506-24
	WP/WSP			When needed	0.0052 lb ai/gal	8033-96
Pre and Post Construction Subterranean Termite Treatment	Liquid	Horizontal barrier	Trenching, rodding, sub-slab injection, crack and crevice (void) injection, excavated soil treatment, spray applications; Foam	When needed	0.0104 lb ai/gal	70506-24, 8033-96
		Vertical barrier			0.002 lb ai/linear ft. or ft of depth	
Outdoor Surfaces and Around Buildings (i.e. foundations, siding, patios, paths, refuse dumps, wood piles, etc.)	RTU Aerosol	Spot, crack and crevice	Aerosol can	When needed	0.06% ai [0.00075 lb ai per 20 oz can]	279-9549
	Liquid, WP/WSP	Broadcast Spot, Crack and Crevice, Perimeter	Sprayers (tank, backpack, handheld, coarse, low pressure), Paint brush	When needed	0.22 lb ai/A or 0.0052 lb ai/gal	70506-24; 8033-96
Ornamental Lawns & Turf - Golf Course	Granular	Broadcast, Spot, Perimeter	Ground	When needed	0.4 lb ai/A	279-9547
	Liquid	Broadcast	Ground	When needed	0.2 lb ai/A	66330-365
Ornamental Lawns & Turf - Residential	Granular	Broadcast, Spot, Perimeter	Ground	When needed	0.20 lb ai/A	279-9547
	Liquid	Broadcast	Ground	When needed	2.3 lb ai/A 0.0052 lb ai/gal	279-3169 and 279-3152
Ornamental Lawns & Turf - Non-residential (institutional, public, commercial or industrial buildings; parks, recreational areas or athletic fields)	Granular	Broadcast, Spot, Perimeter	Ground	When needed	0.4 lb ai/A	279-9547
	Liquid	Broadcast	Ground	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24 and 279-3169
Outdoor Ornamental Trees/Shrubs/Flowers	Granular	Soil Broadcast, Spot, Perimeter	Ground	When needed	0.2 lb ai/A	59369-214
	Liquid, WP/WSP	Foliar, Trunks	Sprayers (tank, backpack, handheld, coarse, low pressure); Paint brush; Soil	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24; 432-1415; 8033-96

Table F.4. Summary of Directions for Non-Agricultural Occupational Uses of Bifenthrin (Existing Uses).						
Use Site	**Formulation**	**Application Type**	**Application Equipment**	**Application Timing**	**Maximum Application Rate**	**Representative Label**
			drench; soil injection			
Interiorscape Ornamentals	Liquid	Foliar, trunks	Sprayers (tank, backpack, handheld, coarse, low pressure); Paint brush	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24
Dry bulk fertilizer for lawns	Liquid	Fertilizer Impregnation	Closed rotary-drum mixer with sprayer	When needed	5.2E-6 lb ai/ft^2 or 0.23 lb ai/A	70506-24
Ant mound	Granular	Spot	Ground	When needed	0.4 lb ai/A	279-9547
	Liquid, WP/WSP	Spot	Sprinkle, Drench	When needed	0.0052 lb ai/gal	70506-24; 8033-96
Wood treatment to in-service poles, posts, and other timber members	RTU Aerosol	Spot, crack and crevice	Aerosol can	When needed	0.06% ai [0.00075 lb ai per 20 oz can]	279-9549
	Liquid RTU	Surface	Brush, Trowel, Pump	When needed	0.04% ai (0.00428 lbs ai/gallon)	75341-14
		Voids	Grease-gun, Pressurized applicator	When needed		
	Liquid, WP/WSP	Spot	Injection, foam, gravity flow, paintbrush, spray	When needed	5.2E-6 lb ai/ft^2 or 0.0052 lb ai/gal	70506-24; 8033-96
Wood treatment to infested wood in attics, crawl spaces, unfinished basements, void areas (termiticide)	Liquid	Spray	Coarse fan sprayer	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24

Appendix G. Summary of Assumptions Used in the Residential Post-Application Assessment

Below is a summary of data that was used in the pyrethroid cumulative and determined to be appropriate for pyrethroid-specific assessments. These data should be considered for all single chemical pyrethroid exposure and risk assessments, including bifenthrin. For some inputs, there is a reasonable amount of pyrethroid specific data in-house. These data were analyzed for use in the 2011 Pyrethroid Cumulative Risk Assessment (CRA)[24] and the single chemical assessments and allow for a deviation from the 2012 Residential SOPs. If the input is not discussed below, then the assessment relies on the 2012 Residential SOPs.

- **Deposited Residue Values:** For the estimated deposited residue values following an indoor perimeter/spot/bedbug, and crack and crevice application of a pyrethroid, it is HED policy to use the collective pyrethroid data available rather than chemical-specific information. The following information was used in the bifenthrin incidental oral post-application exposure algorithms which are derived from the dermal exposure algorithms to calculate exposure following surface directed indoor application:

- *Perimeter/Spot/Bedbug applications (Coarse)*:
  - A default deposited residue value of **2.6 µg/cm²** was used with no adjustment for percent ai. This value is a combination of the pyrethroid data from Keenan (2007) and esfenvalerate data from Selim (2008) for all pyrethroids.
- *Perimeter/Spot/Bedbug applications (Pinstream)*:
  - A default deposited residue value of **1.5 µg/cm²** was used with no adjustment for percent ai. This value is a combination of the pyrethroid data from Keenan (2007) and the ORD Test house date (D390098) for all pyrethroids.
- *Crack and crevice applications*:
  - A default deposited residue value of **0.4 µg/cm²** was used with no adjustment for percent ai. This value is a combination of the pyrethroid data from Keenan (2007), the esfenvalerate data from Selim (2008) and the ORD Test house date (D390098) for all pyrethroids.
- *Mattress Applications:*
  - A deposited residue value of **2.53 µg/cm²** was used to assess exposures resulting from mattress applications based on an application rate of 0.0052 lb ai/gal (see Table 4.4) and assuming 20% of the mattress was treated with bifenthrin.

- **Fraction of Residue Available for Transfer:** Chemical-specific data provided by the Non-Dietary Exposure Task Force (NDETF) were used for the fraction of residue available for transfer (Selim, 2004a; Selim, 2003b; Selim, 2003c; Selim, 2000; Selim, 2002b; Selim, 2002c). The NDETF studies examined the transferability of residues from bare hand-presses on carpets and hard surfaces for deltamethrin, permethrin, and pyrethrins. For carpets, the fraction transferred was 0.03, 0.02 and 0.01 for pyrethrins, permethrin and deltamethrin, respectively. For hard surfaces, the fraction transferred was 0.04, 0.03, and 0.05 for pyrethrins, permethrin, and deltamethrin, respectively. Since the

[24] D394576; Pyrethroid Cumulative Risk Assessment; 10/4/2011

values were so similar across the three chemicals, the average fraction transferred was used for all the pyrethroids in the cumulative assessment: **0.02 for carpets and 0.04 for hard surfaces**.

- **Turf Transferable Residue (TTR) Data:** A TTR study is available for bifenthrin. A HED review of MRID 449552-01 was completed in 2002 (S. Weiss, D284552, 7/31/2002) and an updated regression analysis was completed as part of this assessment. The TTR study was conducted at individual sites in California, Mississippi, and Pennsylvania using a modification of the California Department of Pesticide Regulation (CDPR) designed roller method (Chemosphere, Vol. 22, Nos. 9-10, pp. 975-984, 1991). Talstar®, a flowable concentrate containing 8% active ingredient (ai), was applied using tractor mounted groundboom sprayers to turf. Three applications of 0.2 lb ai/A each were made 21 days apart for a total of 0.6 lb ai/A. TTRs were sampled immediately before and after each application; at 7 and 14 days after treatment (DAT) #1 and #2; and after application #3 at DAT 4, 12, and 24 hours and DAT 2, 4, 7, 10, 21, 28, and 35 days. At each sampling interval, three samples were randomly collected from three treated subplots at each site (9 treated samples total) and the untreated plot. Residues of bifenthrin dissipated quickly during the first few days in all three trials. Total bifenthrin residues at the Georgia site peaked approximately 24 hours after the third application (i.e., mean value of 0.075 $\mu g/cm^2$), and all values dropped to < limit of quantitation (LOQ) after DAT 14. At the California site, residues peaked immediately after the third application (mean value of 0.072 $\mu g/cm^2$), and all values dropped to <LOQ after DAT 10. At the Pennsylvania site, residues peaked immediately after the third application (mean value of 0.063 $\mu g/cm^2$), and all values dropped to <LOQ after DAT 10. The data and the results of the pseudo-first order statistical analysis are summarized below in Table 5.2.1. The predicted DAT0 residue value of 0.061 $\mu g/cm^2$ from the California site was used to estimate risk on turf. The TTR values from the liquid formulation were also used as a surrogate for the registered granular formulations.

Table G.1.: Review of Determination of Transferable Turf Residues on Turf Treated with Bifenthrin (MRID 44955201)

Location	Formulation	Application Rate (lb ai/acre)	Application Method	R-squared	$[C_0]$ ($\mu g/cm^2$)	$[C_0]$ ($\mu g/cm^2$) Predicted	$T_{1/2}$ (days)
GA	Liquid	0.2	Groundboom	0.9423	0.072	0.054	3.1
CA	Liquid	0.2	Groundboom	0.9691	0.072	0.061	2.1
PA	Liquid	0.2	Groundboom	0.91	0.063	0.047	2.2

- **Dislodgeable Foliar Residue (DFR) Data:** A total of four chemical-specific DFR data sets have been submitted for bifenthrin for the following crops: cotton (MRID 421422-01), roses and chrysanthemums (MRID 449552-01), and strawberries (MRID 446844-01). All three studies have been secondary reviewed by HED (see Appendix B). The rose, chrysanthemum, and strawberry datasets were found to be acceptable for risk assessment; however, the cotton was found to be unacceptable due to QA/QC concerns (K. Rickard, D440261 and D441553, 07/19/2017). For the post-application residential

scenarios, HED has used the predicted DFR values from the strawberry study (vs. the chrysanthemum and rose study) because the strawberry study was conducted outdoors (i.e., not in a greenhouse).

The strawberry DFR study was conducted at one site in California. Three applications of the test product (Brigade WSB, a wettable powder (WP) containing 10% ai) were made to strawberry foliage using a retreatment interval of 7 days at target application rate of 0.1 lb ai/A/application for the first application and 0.2 lb ai/A/application for the last two applications, for a total seasonal rate of 0.5 lb ai/A. Spray applications were made using a tractor-mounted sprayer. Leaf samples were collected prior to and immediately following each application (after spray on the crop leaves had dried), 1, 2, and 4 days after the first and second applications and 1, 2, 3, 5, 7, 14, 21, 28, and 35 days after the third (last) application. At each sampling interval, three replicate DFR samples were collected from the treated plot and one sample was collected from the control plot. Average residues of bifenthrin were 0.598 $\mu g/cm^2$ immediately after the third application (0DAT3) and increased to 0.753 $\mu g/cm^2$ at 1DAT. Average residues declined to 0.0248 $\mu g/cm^2$ by the last sampling interval (35DAT3). The data and the results of the pseudo-first order statistical analysis are summarized below in Table 5.2.2. The predicted DAT0 residue value of 0.537 $\mu g/cm^2$ was used to estimate dermal risk from garden/trees. The DFR values from the wettable powder/spray formulation were also used as a surrogate for the registered granular formulations.

Table G.2.: Review of Determination of Dislodgeable Foliar Residues on Strawberry Foliage Treated with Bifenthrin (MRID 44684401)

Location	California
Half-life (days)	7.2
R^2	0.9382
Decay Constant (k)	-0.096
Daily Dissipation (%)	9
Actual Average 0DAT3 ($\mu g/cm^2$)	0.598
Predicted Initial Residue (C_0) ($\mu g/cm^2$)	0.537
% of Application Rate calculated using Actual Average DFR on 0DAT3	26.7
Predicted % of Application Rate (%)	23.9

- **Surface Directed Sprays:** Chemical-specific post-application inhalation exposure data are not available for the registered surface-directed indoor use of bifenthrin; however, HED has received and reviewed an Office of Research and Development (ORD) exposure study that was performed in the U.S. EPA's IAQ Research House (D390098). This study simulated crack and crevice applications of four pesticides; two emulsifiable concentrate products applied via a handheld sprayer (permethrin and cypermethrin), one aerosol can product (propoxur), and one gel bait product (fipronil). The application pattern used in this study is considered a reasonable representation of an indoor crack and crevice application but also can represent other indoor applications such as perimeter (coarse and pinstream) as well as surface directed broadcast uses due to the nature of the

applications (applications were made to floor-to-ceiling paneling on three walls of an interior room). Air concentrations of all four chemicals were collected using stationary air samplers suspended 75 cm above the floor in the room of application (the living room) and two other rooms in the test house (the den and master bedroom). Air samples were collected during the application and 1, 1.5, 2, 2.5, 3, 7, 14, 21, 28, and 35 days after application. Permethrin and cypermethrin air concentrations were not found in any measurable quantities in any room in the research house.

Although the data are not chemical specific, the Non-dietary Exposure Task Force (NDETF) has performed an analysis of all the pyrethroid surface deposition and hand press exposure data that they produced. This analysis shows the exposure data for one pyrethroid can generally be used to represent the entire chemical class. Based on this NDETF analysis and the generally low vapor pressure of pyrethroids, HED believes it is appropriate to use the air concentration data from the ORD study as a surrogate for bifenthrin when applied as a surface-directed application indoors. HED does not have concerns for bifenthrin for the post-application inhalation exposure scenario given that all air concentration values were below the limit of quantitation in the ORD study.

- **Termiticides:** Bifenthrin is also registered for use as a termiticide. Typically, applications are conducted by licensed commercial applicators, however, HED would perform a quantitative assessment for the potential post-application inhalation exposure resulting from a commercial termiticide application in a residential setting. In the case of bifenthrin and other pyrethroids, due to the chemical-physical properties of pyrethroids and their low vapor pressure, it is unlikely that individuals would be exposed to the vapor form of bifenthrin after an application has occurred.