



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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

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SUBJECT: **Bifenthrin:** Revised Draft Human Health Risk Assessment for Registration Review.

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Background

The Pesticide Re-Evaluation Division (PRD) of the Office of Pesticide Programs (OPP) has requested that the Health Effects Division (HED) update the most recent draft human health risk assessment (DRA) conducted in support of Registration Review (K. Rickard, D434404 and D436605, 08/29/2017). The most recent human health risk assessment for bifenthrin was conducted in 2017 in support of both Registration Review *and* Section 3 Registration of requested new uses under petition 6E8482 (in/on 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; including crop group conversion of citrus group 10-10, caneberry subgroup 13-07A, and tree nut group 14-12).

This memorandum serves as HED's update to the 2017 DRA only and includes crop group conversions for currently registered commodities under CFR 180.442 (a). This assessment also includes the established tolerances for current Section 18 Emergency Exemptions [CFR 180.442 (b)] in/on apple, avocado, nectarine, peach, and pomegranate. Unlike the previous (2017) DRA, this updated DRA excludes previously proposed tolerances and requested pre-harvest interval (PHI) reduction for *Brassica* leafy greens subgroup 4-16B identified for Section 3 Registration under petition 6E8482.

In addendum to the previous 2017 DRA, the following updates and revisions are incorporated into the corresponding dietary, occupational, residential, and aggregate human health risk assessments for the existing uses of bifenthrin:

- This revised DRA considers only the currently registered uses of bifenthrin. The dietary, occupational, and residential exposure assessments have been updated to exclude the proposed new uses of bifenthrin requested under petition 6E8482.
- The Food Quality Protection Act (FQPA) uncertainty factor is reduced from 3X to 1X for children less than 6 years old (for all pyrethroids including bifenthrin).
- The bifenthrin dermal point of departure (POD) has been updated to include an adjustment using a rat:human absorption ratio.
- The dietary assessment for the registered uses of bifenthrin has been revised using updated Screening Level Usage Analysis (SLUA) information, updated USDA Pesticide Data Program (PDP) monitoring data, and the reduction of the FQPA uncertainty factor from 3X to 1X for children less than 6 years old.
- The registered residential uses of bifenthrin are reevaluated using the updated dermal POD, the reduction of the FQPA uncertainty factor from 3X to 1X for children less than 6 years old, reduced turf application rates, and an additional granular turf transferrable residue (TTR) study.
- The aggregate exposure assessments are revised to include the resulting updated dietary and residential exposure estimates.
- The registered occupational uses of bifenthrin are reevaluated using the updated dermal POD and the submitted granular TTR study.

This memorandum summarizes the updated dietary, occupational, residential, and aggregate human health risk assessments conducted in support of Registration Review.

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1.0 Executive Summary

HED has updated the most recent DRA (K. Rickard, D434404 and D436605, 08/29/2017) for bifenthrin conducted in support of Registration Review. The aforementioned updates are incorporated into the corresponding dietary, occupational, residential, and aggregate human health risk assessments for the existing uses of bifenthrin.

Use Profile: 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 (EPs). Most of the registered products are applied 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 EPs 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.

Exposure Profile: Acute and chronic dietary (food and drinking water) exposures are expected from the existing uses of bifenthrin. Non-dietary exposure to bifenthrin may occur from occupational and residential exposure sources. Occupational (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). Residential exposures and exposures from spray drift are expected to be short-term only. However, bifenthrin does not increase in toxicity with repeated dosing, therefore, only single day exposures are assessed.

Hazard Considerations: The toxicology database for bifenthrin is considered complete with respect to guideline toxicity studies. Bifenthrin is a Type I pyrethroid, and, like other pyrethroids, causes neurotoxicity from interaction with sodium channels leading to clinical signs of neurotoxicity. The metabolic profiles for all the pyrethroids are very similar marked by rapid absorption, metabolism, and time-to-peak effect. The single-dose and repeated-dose bifenthrin studies show that repeat exposures do not result in lower points of departure (PODs) (i.e., there is no evidence of increasing toxicity with an increased duration of exposure). Therefore, the exposure assessments are conducted as a series of acute exposures, and these are protective of scenarios in which exposure occurs for multiple days.

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), incidental oral, and episodic ingestion scenarios. 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 dermal risk assessment, the POD is based on exaggerated hind limb flexion seen in the 21-day dermal rat study. This POD from a route-specific dermal toxicity study was adjusted using a rat:human absorption ratio.

For inhalation risk assessment, the POD is based on tremors and increased respiration rates seen in the 28-day inhalation toxicity study. Human Equivalent Concentrations (HECs)/Human Equivalent Doses were calculated for residential and occupational scenarios.

Previously, OPP used a 3X Food Quality Protection Act (FQPA) safety factor (SF) based on concerns for pharmacokinetic differences between adults and children (Scollon, 2011). OPP has re-evaluated the need for an FQPA safety factor for human health risk assessments for pyrethroid pesticides. Consistent with EPA's 2014 Guidance for Applying Quantitative Data to Develop Data Derived Extrapolation Factors (DDEF) for Interspecies and Intraspecies Extrapolation, the Agency considers the FQPA safety factor as having two components: with 3X assigned to pharmacokinetics (PK) and 3X to pharmacodynamic (PD) differences. The previous conclusion that the PD contribution to the FQPA factor is 1X remains the same. Based on a review of the available guideline and literature studies, as well as data from the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA) program, the Agency concludes that the PK contribution to the FQPA factor is also 1X for adults, including women of child-bearing age, and children. Therefore, the total FQPA safety factor for pyrethroids can be reduced to 1X for all populations.¹

A total uncertainty factor of 100X (10X to account for interspecies extrapolation, and 10X for intra-species variation, and 1X FQPA safety factor) is applicable to oral and dermal exposures resulting in a level of concern (LOC) of 100. A total uncertainty factor of 30X [3X due to the calculation of HECs accounting for pharmacokinetic (not pharmacodynamic) interspecies differences, and 10X for intra-species variation, and 1X FQPA safety factor] is applicable to inhalation exposures resulting in a LOC of 30. Since the toxicological endpoints for dermal, oral, and inhalation are based on the same effects (neurotoxicity), the risks from these exposure routes can be combined when appropriate. Since the LOC for oral and dermal (100) is not the same as for inhalation (30), when combining those routes with inhalation exposures, it is appropriate to use an Aggregate Risk Index (ARI) approach. The LOC for the ARI approach is 1.

HED has classified bifenthrin as "possible human carcinogen" on the basis of a mouse study in which the high-dose males showed an increased incidence of urinary bladder tumors. The Agency has determined that quantification of risk using a non-linear approach [i.e., reference dose (RfD)] will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to bifenthrin (TXR 0051809, Carcinogenicity Peer Review Committee, 01/22/1992).

Residue Chemistry: The bifenthrin residue chemistry database is complete, and adequate analytical methods and standards are available for tolerance enforcement. The residue of concern in plants and livestock is bifenthrin for both tolerance enforcement and risk assessment.

¹ USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review (2019). <https://www.epa.gov/ingredients-used-pesticide-products/2019-evaluation-fqpa-safety-factor-pyrethroids>.

The residue of concern in drinking water is bifenthrin only. Permanent tolerances are established for bifenthrin in/on a number of food commodities listed under 40 CFR §180.442(a)(1). A tolerance of 0.05 ppm (the method limit of quantitation: LOQ) is also listed under §180.442(a)(2) for the use of bifenthrin in food handling establishments (FHEs). There are also time-limited tolerances for apple, avocado, nectarine, peach, and pomegranate established under §180.442(b) following Section 18 emergency exemptions with expiration dates of 12/31/2019 through 12/31/2021. Tolerances with regional registrations are also established on grass forage and hay for bifenthrin under §180.442(b).

Dietary Exposure and Risk Assessment: Highly refined acute and chronic (average) dietary (food and drinking water) exposure and risk assessments were conducted for bifenthrin. The assessments were refined using USDA Pesticide Data Program (PDP) monitoring data, field trial data, percent crop treated (PCT) estimates, and empirical processing factors, where available. The estimated drinking water concentration (EDWC) is based on the bifenthrin limit of solubility (0.014 µg/L). There are no acute dietary (food and drinking water) risk estimates of concern for the U.S. population and all population subgroups for the existing uses of bifenthrin [all risk estimates are <100% of the acute population-adjusted dose (aPAD)]. At the 99.9th percentile of exposure, the acute dietary risk estimate is 4.6% of the aPAD for the general U.S. population and 9.6% of the aPAD for all infants (< 1 year old), the most highly exposed population subgroup. The chronic exposure assessment was conducted solely for the purpose of obtaining average dietary exposure values for use in the aggregate assessment. The population subgroup with the highest average dietary exposure estimate is children 1-2 years old (0.000121 mg/kg/day).

Residential Exposure and Risk Assessment: 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 for the registered uses of bifenthrin. All of the residential handler combined (dermal + inhalation) ARIs are not of concern (ARIs are greater than the LOC of 1).

Bifenthrin-specific turf transferrable residue (TTR; liquid and granular) and dislodgeable foliar residue (DFR; liquid) data are available and were used in the residential-post-application assessment where appropriate. Post-application dermal, and/or incidental oral margin of exposures (MOEs) were not of concern following indoor treatments, treatments (shampoos) to dogs, and treatments to lawns/turf with the exception of the maximum registered application rate for liquid formulations on lawns/turf (2.3 lb ai/A). For adults, the following scenarios resulted in risk estimates of concern at the application rate of 2.3 lb ai/A: dermal exposures from high contact activities on treated lawns/turf (dermal MOE = 69, LOC = 100). For children (1 to < 2 years old), the following scenarios resulted in risk estimates of concern at the application rate of 2.3 lb ai/A: dermal exposures from high contact activities following liquid application to lawns/turf (MOE = 35, LOC = 100); incidental oral (hand-to-mouth) exposures following liquid applications to lawns/turf (MOE = 32, LOC = 100); and combined dermal and hand-to-mouth exposures following liquid applications to lawns/turf (MOE = 17, LOC = 100). PRD also

requested that HED evaluate a lower application rate of 0.23 lb ai/A for liquid/spray formulations of bifenthrin on residential turf since there may be some discrepancy with the current maximum labeled rate of 2.3 lb ai/A. There were no risk estimates of concern for adults and children from exposure following liquid applications of bifenthrin at a rate of 0.23 lb ai/A (all MOEs are greater than the LOC of 100).

In addition, a risk estimate of concern was identified for episodic granular ingestion following granular application to lawns/turf (MOE = 85, LOC = 100) assuming the maximum % ai in registered granular formulations of bifenthrin (0.2%), a maximum application rate of 200 lb product/A (0.50 lb ai/A), and ingestion rates adjusted for bifenthrin-specific application rates.² This scenario is not of concern (MOE=100) when assuming a maximum application rate of 170 lbs product/A (0.34 lb ai/A).

Aggregate Exposure and Risk Assessment: The acute aggregate assessment is equivalent to the acute dietary (food and drinking water) exposure and risk estimates; there are no acute aggregate risk estimates of concern.

There are no short-term aggregate (food, drinking water, and residential combined) risk estimates of concern (i.e., all aggregate MOEs are greater than the LOC of 100) when aggregating residential exposures that were not of concern by themselves. Residential exposures that were of concern [i.e., high contact activities on treated turf for adults and children at maximum labeled rates for liquid formulations (2.3 lb ai/A)] were not aggregated because the additional exposure from food and water would only increase the risk estimates. Therefore, an aggregate assessment was conducted for the residential scenarios that resulted in the highest exposure without a risk concern. In addition, because of a possible discrepancy in the label rates, an aggregate assessment was also performed for adults and children (1 to < 2 years old) performing high contact activities on treated turf assuming a lower maximum application rate of 0.23 lb ai/A for liquid/spray formulations of bifenthrin on residential turf.

The short-term aggregate assessment for adults resulted in MOEs of 1,100 (treated gardens) and 520 (treated turf at 0.23 lb ai/A). The short-term aggregate assessment for children 1 to <2 years old resulted in MOEs of 490 (treated carpets/mattresses) and 170 (treated turf at 0.23 lb ai/A). The short-term aggregate assessment for children 6 to < 11 years old and children 11 to 16 years old resulted in MOEs of 1,600 (treated gardens) and 7,700 (golfing), respectively.

Non-Occupational Spray Drift Exposure and Risk Assessment: A quantitative spray drift assessment was conducted for 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 at the maximum rate of 2.3 lb ai/A; therefore, they cannot be considered protective of potential spray drift exposures. For the quantitative spray drift assessment, there were no dermal risk estimates of concern for adults or combined dermal

² The assumed ingestion rate for dry pesticide formulations (e.g., pellets and granules) is 0.3 gram/day for children 1 < 2 years old. It is assumed that if 150 pounds of product were to be applied to a ½ acre lawn, the amount of product per square foot would be approximately 3 g/ft² and a child would consume one-tenth of the product available in a square foot. This rate has been refined with product-specific information to reflect the amount of product applied on a per area basis (200 lb product applied per acre to result in an ingestion rate of 0.2 g/day).

and incidental oral risk estimates of concern for children 1 to < 2 years old at the field edge assuming screening-level droplet sizes and boom heights (MOEs are greater than the LOC of 100).

Occupational Handler Exposure and Risk Assessment: 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 the addition of PPE specified on most representative labels (chemical resistant or waterproof gloves).

Occupational Post-Application Exposure and Risk Assessment: All dermal post-application exposures were not of concern (MOE ≥ 100) on the day of application using bifenthrin-specific DFR and TTR data and assuming maximum application rates and transfer coefficients (TCs) for each scenario. 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."³

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.

2.0 Risk Assessment Conclusions and Recommendations

Dietary (food and drinking water) exposure and risk estimates are not of concern for the existing uses of bifenthrin.

There are no residential handler risk estimates of concern for bifenthrin. There are no residential post-application risk estimates of concern for adults or children, except for the following:

- episodic ingestion of granules, assuming the maximum % ai in registered granular formulations of bifenthrin (0.2%), a maximum application rate of 200 lb product/A, and ingestion rates adjusted for bifenthrin-specific application rates, for children 1 to < 2 years old. This scenario is not of concern assuming a maximum application rate of 170 lbs product/A (0.34 lb ai/A).

³ <https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice>

- exposures from high contact activities on treated turf for adults and children at maximum labeled rates for liquid formulations (2.3 lb ai/A). This scenario is not of concern assuming a maximum rate of 0.23 lb ai/A.

There are no acute aggregate (food and drinking water) risk estimates of concern. There are no short-term aggregate (food, drinking water, and residential) risk estimates of concern when aggregating residential exposures that were not of concern. Residential exposures 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.

Two scenarios result in occupational handler risk estimates of concern assuming baseline attire but are not of concern with the addition of representative label-specified PPE (gloves). There are no occupational post-application risk estimates of concern on the day of application.

2.1 Data Deficiencies

None.

2.1.1 Enforcement Analytical Method

Adequate tolerance enforcement analytical 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 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

The current tolerance expression for bifenthrin is correct (40 CFR §180.442):

Tolerances are established for residues of the insecticide bifenthrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate.

During registration review, HED implements crop group conversions and commodity definition revisions for existing tolerances resulting from changes to pesticide crop grouping regulations. HED is recommending the following crop group conversions: brassica head and stem subgroup 5A (except cabbage) to vegetable head and stem brassica group 5-16; brassica leafy greens subgroup 5B to brassica leafy greens subgroup 4-16B; caneberry subgroup 13A to caneberry subgroup 13-07A; leafy petioles subgroup 4B to leaf petiole vegetable subgroup 22B; citrus fruit

group 10 to citrus fruit group 10-10; and tree nut group 14 to tree nut group 14-12. HED is also recommending correcting the commodity definitions for cilantro, milk, grass forage, and grass hay.

There are several crops with U.S. tolerance levels that are different than Canada and/or Codex maximum residue limits (MRLs) (see section 2.1.3 International Harmonization below). For the purpose of harmonization, the U.S. tolerances for bifenthrin which are lower than those established by Canada and/or Codex should be raised for alignment. HED also recommends that the following established tolerances be revised to be consistent with the Organization for Economic Co-operation and Development (OECD) rounding class practice: almond hulls at 2 ppm, globe artichoke at 1 ppm, avocado at 0.5 ppm, cattle fat at 1 ppm, coriander seed at 5 ppm, field corn forage at 3 ppm, pop corn stover at 5 ppm, sweet corn forage at 3 ppm, sweet corn stover at 5 ppm, hog fat at 1 ppm, horse fat at 1 ppm, okra at 0.5 ppm, pomegranate at 0.5 ppm, sheep fat at 1 ppm, soybean hulls at 0.5 ppm, soybean refined oil at 0.3 ppm, and root vegetable subgroup 1B at 0.1 ppm.

The recommended revisions for the 40 CFR §180.442(a) *General* tolerances based on the registration review of bifenthrin are summarized below in Table 2.1.2.1.

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Almond, hulls	2.0	2	Corrected value to be consistent with OECD Rounding Class Practice.
Artichoke, globe	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Beet, garden, leaves	-	15	Commodity definition revision.
Beet, garden, tops	15	remove	
Beet, garden, roots	0.45	0.5	Harmonization with Canada.
Broccoli, chinese	0.6	4	Crop group conversion/revision. ^{1,2} Harmonization with Canada.
Brassica, leafy greens, subgroup 4-16B	-	4	Crop group conversion/revision. ¹ Harmonization with Canada.
Brassica, leafy greens, subgroup 5B	3.5	remove	
Bushberry, subgroup 13-07B	1.8	3	Harmonization with Codex and Canada.
Cabbage	4.0	7	Harmonization with Canada.
Caneberry subgroup 13-07A	-	1	Crop group conversion/revision. Corrected value to be consistent with OECD Rounding Class Practice.
Caneberry subgroup 13A	1.0	remove	
Cattle, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Cattle, meat byproducts	0.10	0.2	Harmonization with Codex.
Cattle, meat	0.5	3	Harmonization with Codex.
Celtuce	-	3	Crop group conversion/revision. ^{1,3}
Cilantro, dried leaves	-	25	Commodity definition revision.
Coriander, dried leaves	25	remove	
Cilantro, fresh leaves	-	6	Commodity definition revision. Corrected value to be consistent with OECD Rounding Class Practice.
Coriander, fresh leaves	6.0	remove	

Table 2.1.2.1. Summary of Tolerance Revisions for Bifenthrin (40 CFR §180.442(a) General).			
Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Coriander, seed	5.0	5	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, field, forage	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, field, stover	5.0	15	Harmonization with Codex.
Corn, pop, stover	5.0	5	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, sweet, forage	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, sweet, stover	5.0	5	Corrected value to be consistent with OECD Rounding Class Practice.
Eggplant	0.05	0.3	Harmonization with Codex.
Fennel, florence, fresh leaves and stalk	-	3	Crop group conversion/revision. ^{1,3}
Fruit, citrus, group 10-10	-	0.05	Crop group conversion/revision.
Fruit, citrus, group 10	0.05	remove	
Goat, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Goat, meat byproducts	0.10	0.2	Harmonization with Codex.
Goat, meat	0.5	3	Harmonization with Codex.
Grape	0.2	0.3	Harmonization with Codex.
Hog, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Hog, meat byproducts	0.10	0.2	Harmonization with Codex.
Hog, meat	0.5	3	Harmonization with Codex.
Hop, dried cones	10.0	20	Harmonization with Codex.
Horse, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Horse, meat byproducts	0.10	0.2	Harmonization with Codex.
Horse, meat	0.5	3	Harmonization with Codex.
Kohlrabi	-	3	Crop group conversion/revision. ^{1,3}
Leaf petiole vegetable subgroup 22B	-	3	Crop group conversion/revision. ^{1,3}
Leafy petioles subgroup 4B	3	remove	
Lettuce, head	3.0	4	Harmonization with Canada.
Mayhaw	1.4	1.5	Harmonization with Canada.
Milk	0.1	0.2	Commodity definition revision. Harmonization with Codex.
Milk, fat	1.0	3	Commodity definition revision. Harmonization with Codex.
Milk, fat (reflecting 0.1 ppm in whole milk)			
Nut, tree, group 14-12	-	0.05	Crop group conversion/revision.
Nut, tree, group 14	0.05	remove	
Pistachio	0.05	remove	
Okra	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.
Pear	0.5	0.9	Harmonization with Canada.
Sheep, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Sheep, meat byproducts	0.1	0.2	Harmonization with Codex.
Sheep, meat	0.5	3	Harmonization with Codex.

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Soybean, hulls	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.
Soybean, refined oil	0.30	0.3	Corrected value to be consistent with OECD Rounding Class Practice.
Spinach	0.2	0.3	Harmonization with Canada.
Strawberry	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Swiss chard	-	3	Crop group conversion/revision. ^{1,3}
Turnip, greens	3.5	remove	Crop group conversion/revision. ¹
Tomato	0.15	0.3	Harmonization with Codex.
Vegetable, brassica, head and stem, group 5-16	-	0.9	Crop group conversion/revision. ¹
Brassica, head and stem, subgroup 5A	0.6	remove	Harmonization with Canada.
Vegetable, cucurbit, group 9	0.4	0.5	Harmonization with Canada.
Vegetable, legume, edible podded, subgroup 6A	0.6	0.8	Harmonization with Canada.
Vegetable, root, subgroup 1B, except sugar beet and garden beet	0.10	0.1	Corrected value to be consistent with OECD Rounding Class Practice.

¹ The recommended conversion of existing tolerances in/on crop subgroup 4B to crop subgroup 22B (leafy petioles), crop subgroup 5B to crop subgroup 4-16B (*Brassica* leafy greens), and crop subgroup 5A to crop group 5-16 (vegetable, *Brassica*, head and stem), kohlrabi, and Chinese broccoli are consistent with the document entitled, "Attachment - Crop Group Conversion Plan for Existing Tolerances as a Result of Creation of New Crop Groups under Phase IV (4-16, 5-16, and 22)" dated 11/3/2015.

² HED is recommending for individual tolerances of 0.6 ppm for Broccoli, Chinese and Kohlrabi based on the currently established tolerance for these commodities as part of crop group 5A.

³ HED is recommending for individual tolerances of 3 ppm for Celtuce, Florence fennel and Swiss chard based on the currently established tolerance for these commodities as part of crop subgroup 4B.

For the 40 CFR §180.442(b) *Section 18 emergency exemption* tolerances, the recommended revisions based on the registration review of bifenthrin are summarized below in Table 2.1.2.2.

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Avocado	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.
Pomegranate	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.

For the 40 CFR §180.442(c) *Tolerances with regional registration*, the recommended revisions based on the registration review of bifenthrin are summarized below in Table 2.1.2.3.

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Grass, forage, fodder and hay, group 17, forage	-	4	Commodity definition correction. Corrected value to be consistent with OECD Rounding Class Practice.
Grass, forage	4.0	remove	
Grass, forage, fodder and hay, group 17, hay	-	15	Commodity definition correction.
Grass, hay	15	remove	

2.1.3 International Harmonization

The International Residue Limit (IRL) summary for bifenthrin is shown in Appendix E. There are MRLs set by Canada and Codex on a number of established uses registered in the U.S. Mexico adopts U.S. tolerances and/or Codex MRLs for its export purposes. The U.S., Canadian, and Codex residue definitions are harmonized (parent only). However, a review of the established bifenthrin tolerances finds there are a number of differences between U.S. tolerances and the MRLs set by Canada and Codex on several crops. For the purpose of harmonization, the tolerances should be raised for garden beet roots to 0.5 ppm, Chinese broccoli to 4 ppm, brassica head and stem subgroup 4-16B to 0.9 ppm, bushberry subgroup 13-07A to 3 ppm, cabbage to 7 ppm, cattle meat byproducts to 0.2 ppm, cattle meat to 3 ppm, field corn stover to 15 ppm, eggplant to 0.3 ppm, goat meat byproducts to 0.2 ppm, goat meat to 3 ppm, grape to 0.3 ppm, hog meat byproducts to 0.2 ppm, hog meat to 3 ppm, hops to 20 ppm, horse meat byproducts to 0.2 ppm, horse meat to 3 ppm, head lettuce to 4 ppm, mayhaw to 1.5 ppm, milk to 0.2 ppm, milk fat to 3 ppm, pear to 0.9 ppm, sheep meat byproducts to 0.2 ppm, sheep meat, to 3 ppm, spinach to 0.30 ppm, tomato to 0.3 ppm, brassica head and stem vegetable group 5-16 to 0.9 ppm, cucurbit vegetable group 9 to 0.50 ppm, and vegetable legume edible podded subgroup 6A to 0.80 ppm. All U.S. tolerances on corn raw agricultural commodities (RACs) are therefore harmonized with international MRLs to the greatest extent possible.

2.2 Label Recommendations

2.2.1 Residue Chemistry

- HED recommends that, if needed, labels be revised to ensure that they reflect the appropriate crops/crop groupings as a result of the crop group conversions recommended above in Section 2.1.2.

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 (e.g., treatment of stored products and treatment for carpet beetles) and use on lawns/turf


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 seed treatment scenarios that 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. There are also several non-seed treatment occupational handler scenarios that require the use of gloves to result in risk estimates not of concern. Gloves as PPE are specified on most registered representative bifenthrin labels.
- 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)-(1R,3R)-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

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-m³/mol) suggests

that it is expected to volatilize from water and wet soil. However, 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); 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 EP labels and use sites (with the highest application rates or percent ai) was identified by HED and reviewed by the Biological and Economic Analysis Division (BEAD) and is provided in Appendix F (Tables F.1 – Table F.3). Table F.1 presents the registered EPs 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.2 summarizes the existing agricultural uses of bifenthrin, and Table F.3 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 EPs 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.

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 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).

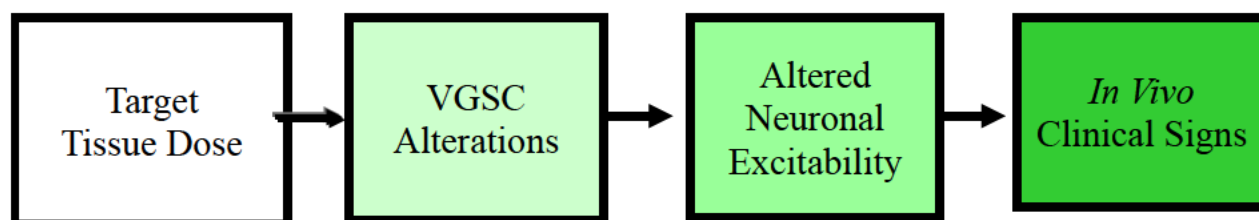


Figure 4.0. Adverse outcome pathway for pyrethroids

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 ED₅₀ 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 ED₅₀ value of motor activity by a factor of two (Wolansky *et al.*, 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 lowest observed adverse effect level (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. 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 (D. Smegal, TXR 0056209, 04/26/2012; U. Habiba, 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 ()
- 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. In addition to these available studies, HED's Management Team assigned a workgroup to conduct a systematic review of publicly available literature on pyrethroids (Memo, R. McGovern *et al.*, D448870, 04/11/2019). The objective was to identify studies which would potentially have an impact upon the route-specific endpoints used in pyrethroid human health risk assessments. Identification of these studies involved a tiered review approach to eliminate studies which did not meet specific requirements for methodology, test subjects, test substances, relevance to

human exposures, and dose levels sufficiently low to potentially result in the selection of lower points of departure (PODs) used for individual pyrethroid risk assessments. Studies found to pass the screening criteria were forwarded to the appropriate pyrethroid risk assessment teams for consideration. Following HED's tiered screening criteria, no studies were identified for bifenthrin to be considered for risk assessment.

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 mode-of-action (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 of 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 no observed adverse effect level (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 dietary 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 “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.

Bifenthrin has low acute toxicity via the dermal and inhalation routes (Category III) of exposure and has high acute toxicity via the oral route (Category I). It is not a skin irritant, but is a moderate eye irritant and is a dermal sensitizer.

4.3 Safety Factor for Infants and Children (FQPA Safety Factor)⁴

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

FFDCA section 408 requires the Agency to apply an additional 10X safety factor to account for the potential pre- and post-natal toxicity and completeness of the data with respect to infants and children unless, based on reliable data, EPA can conclude that another safety factor will be “safe.” The Agency considers the FQPA safety factor as having two components, with 3X assigned to pharmacokinetic (PK) and 3X to pharmacodynamic (PD) differences. Previously, EPA’s Office of Pesticide Programs (OPP) retained a 3X FQPA Safety Factor (1X for PD and 3X for PK differences) for children < 6 years old based on concerns for PK differences between adults and children (E. Scollon, TXR 0056045, D381210, 06/27/2011). OPP has re-evaluated the need for an FQPA Safety Factor for human health risk assessments for pyrethroid pesticides based on a review of the available guideline and literature studies as well as data from the CAPHRA program. Because no new information of suitable quality was available on the age-related PD properties of the pyrethroids, the PD contribution to the FQPA safety factor remains at 1X. Regarding PK, recent data including human physiologically based pharmacokinetic (PBPK) models as well as *in vivo* and *in vitro* data on protein binding, enzyme ontogeny, and metabolic clearance, support the conclusion that the PK contribution to the FQPA safety factor can be reduced to 1X for all populations.⁵ Therefore, the Agency concludes that the default 10X

⁴ 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>).

⁵ USEPA Office of Pesticide Programs’ Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review (2019). <https://www.epa.gov/ingredients-used-pesticide-products/2019-evaluation-fqpa-safety-factor-pyrethroids>

FQPA safety factor can be reduced to 1X for all populations for the pyrethroid pesticides (E. Craig, D455401, 12/12/2019).

4.4 Toxicity Endpoint and Point of Departure Selections

4.4.1 Dose Response Assessment

The details for selecting toxicity endpoints and PODs for various exposure scenarios are presented in Appendix A.2. Based on the 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 WOE evaluation. In addition to the typical guideline studies, data from two special studies (Wolansky study on locomotor activity and Nemeč/WIL FOB study) evaluating neurobehavioral outcomes are available for bifenthrin (Nemeč 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 Nemeč/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 Nemeč/WIL study (Nemeč 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 A.2.2 in the Appendix). 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 POD.

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.

Short-term Dermal: Quantification of dermal risks was performed using a 21-day dermal rat study with a BMDL₁₀ value of 96.3 mg/kg/day and a BMD₁₀ value of 187.0 mg/kg/day based on exaggerated hind limb flexion (see Appendix A.3 for the BMD analysis). This POD from a route-specific dermal toxicity study was adjusted using a rat:human absorption ratio (45.5%/26.2% = 1.7) from the 100 nmol application dose tested in rats and humans in an *in vitro* dermal study (MRID 50981601). The rat and human dermal absorption values were based on the sum of tape strip results (individual results were not available), receptor fluid and skin residues. Adjusting the dermal POD with the ratio of 1.7 yields an adjusted dermal POD of 163.7 mg/kg/day.

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.

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.

4.4.2 Recommendation for Combining Routes of Exposure for Risk Assessment

HED combines risk estimates 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.

4.4.3 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. Although 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 (81.3 mg/kg/day). The Agency has determined that quantification of risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to bifenthrin (TXR 0051809, Carcinogenicity Peer Review Committee meeting on bifenthrin, 01/22/1992).

4.4.4 Points of Departure and Toxicity Endpoints Used in Human Health Risk Assessment for Bifenthrin

Exposure Scenario	POD	Uncertainty/FQPA Safety Factors	LOC	Study and Toxicological Effects
Acute Dietary- (All Populations)	BMDL _{1SD} = 3.1 mg/kg	U _F A = 10X U _F 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	BMDL _{1SD} = 3.1 mg/kg	U _F A = 10X U _F H = 10X FQPA SF = 1X	LOC = 100	
Short-Term (1-30 days) Dermal	BMDL ₁₀ = 96.3 mg/kg/day (adjusted dermal POD = 163.7 mg/kg/day) ^a	U _F A = 10X U _F H = 10X FQPA SF = 1X	LOC = 100	21-day dermal study in rats. MRID 45280501 BMD ₁₀ = 187.0 mg/kg/day, based on exaggerated hind limb flexion
Short-Term (1-30 days) Inhalation	NOAEL = 0.0059 mg/L/day ^b	U _F A = 3X U _F 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, 01/22/1992).			

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

^a96.3 mg/kg/day x 1.7

^bHuman equivalent concentration (HEC) and human equivalent doses (HED) are summarized in Table 4.4.4.3

Exposure Scenario	POD	Uncertainty/FQPA Safety Factors	LOC	Study and Toxicological Effects
Short-Term (1-30 days) Dermal	BMDL ₁₀ =96.3 mg/kg/day (adjusted dermal POD = 163.7 mg/kg/day) ^a	U _{FA} = 10X U _{FH} = 10X	LOC = 100	21-day dermal study in rats. MRID 45280501 BMD ₁₀ =187.0 mg/kg/day, based on exaggerated hind limb flexion
Short-Term (1-30 days) Inhalation	NOAEL = 0.0059 mg/L/day ^b	U _{FA} = 3X U _{FH} = 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, 01/22/1992).			

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

^a96.3 mg/kg/day x 1.7

^bHuman equivalent concentration (HEC) and human equivalent doses (HED) are summarized in Table 4.4.4.3

Population	Scenario	Toxicity duration adjustment ¹		HEC		HED
		Daily	Weekly	mg/L	mg/m ³	(mg/kg-day)
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. HED = human equivalent dose. 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.

4.5 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 FFDCFA 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, 2013⁶ 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.⁷

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. 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 bifenthrin. The residue of concern in drinking water is bifenthrin.

Matrix		Residues for Risk Assessment ¹	Residues for Tolerance Expression ¹
Plants	Primary Crop	Bifenthrin	Bifenthrin
	Rotational Crop		
Livestock	Ruminant		
	Poultry		
Drinking Water		Bifenthrin	N/A ²

¹ Bifenthrin = [(2-methyl[1,1-biphenyl]3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropanecarboxylate]

² N/A – Not Applicable.

⁶ See <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

⁷ <https://www.epa.gov/endocrine-disruption>

5.2 Food Residue Profile

The bifenthrin residue chemistry database is complete, and adequate analytical methods and standards are available for tolerance enforcement. The enforcement method LOQ for crop and livestock commodities is 0.05 ppm. Bifenthrin is typically applied as a foliar application for later season uses. Metabolism data show that when applied foliarly, the vast majority of residue is likely to be surface residues at the site of application consisting primarily of unchanged parent compound. Applications directly to soil generally do not result in significant residues in plants due to bifenthrin's affinity to bind to soil, its low soil mobility, and the low tendency of this pesticide to translocate within plants. The available magnitude of the residue data show that when following the registered patterns of use, detectable residues of bifenthrin are expected in crops. Decline study data show variable results, but generally indicate that residue levels do decline with time. Empirical processing data indicate that residues of bifenthrin can concentrate in some processed commodities. For bifenthrin, there are several livestock feedstuffs registered for use. Because bifenthrin residues are found to transfer to livestock tissues, tolerances are established on several livestock commodities. There are no tolerances established for residues of bifenthrin in or on rotational crops and none are needed at this time.

5.3 Water Residue Profile

The Environmental Fate and Effects Division's (EFED) most recent drinking water assessment for bifenthrin (Z. Ruge, D453185, 07/12/2019) confirmed that the EDWC for use in the dietary exposure assessment is the bifenthrin limit of solubility of 0.014 µg/L.

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, percent crop treated (%CT) data, and empirical processing factors, where available. 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

BEAD provided a Screening Level Usage Analysis (SLUA) for bifenthrin that is dated

September 18, 2019 (updated 02/11/2020). Additional %CT data for beans (succulent), bushberries (all), citron and citrus hybrids, eggplant, kumquat, limes, nectarines, okra, peas (succulent), non-bell peppers, and pummelo were provided by BEAD in the March 23, 2020 memorandum, “*Bifenthrin Usage Analysis in Support of Human Health Risk Assessment for Registration Review (Revised)*” provided by A. Lenner and N. Mallampalli.

Using this information, the following maximum %CT estimates for bifenthrin were used to refine the acute dietary risk assessment for the following crops: almonds: 40%, apples: 10%, artichoke: 65%, green beans (fresh & succulent): 60%, blueberries (all bushberries): 35%, broccoli: 25%, Brussel sprouts: 5%, cabbage: 50%, caneberries: 55%, canola: 25%, cantaloupes: 55%, carrots: 5%, cauliflower: 2.5%, celery: 45%, chicory: 5%, citrus (all others): 2.5%, corn: 10%, cotton: 20%, cucumbers: 35%, dry beans/peas: 5%, eggplant: 45%, grapefruit: 2.5%, grapes, juice: 10%, grapes, table: 2.5%, grapes, wine: 5%, hazelnuts: 5%, honeydews: 90%, kumquat: 2.5%, lemons: 2.5%, lettuce: 15%, lima beans: 40%, lime: 2.5%, nectarines: 10%, okra: 45%, onions: 5%, oranges, 10%, peaches: 10%, peanuts: 20%, pears: 2.5%, green peas (fresh & succulent): 50%, pecans: 20%, peppers (all): 30%, pistachios: 55%, pomegranate: 40%, potatoes: 15%, pummelo: 2.5%, pumpkins: 25%, soybeans: 10%, spinach: 15%, squash: 25%, strawberries: 70%, sweet corn: 50%, tangerines: 2.5%, tomatoes: 45%, walnuts: 25%, watermelons: 20%.

The following average %CT estimates for bifenthrin were used to refine the chronic dietary risk assessment for the following crops: almonds: 25%, apples: 2.5%, artichoke: 30%, green beans (fresh & succulent): 55%, blueberries (all bushberries): 10%, broccoli: 15%, Brussel sprouts: 1%, cabbage: 30%, caneberries: 45%, canola: 10%, cantaloupes: 50%, carrots: 2.5%, cauliflower: 1%, celery: 10%, chicory: 2.5%, citrus (all others): 1%, corn: 5%, cotton: 15%, cucumbers: 20%, dry beans/peas: 2.5%, eggplant: 25%, grapefruit: 1%, grapes, juice: 2.5%, grapes, table: 1%, grapes, wine: 2.5%, hazelnuts: 1%, honeydews: 25%, kumquat: 1%, lemons: 1%, lettuce: 10%, lima beans: 20%, lime: 1%, nectarines: 2.5%, okra: 25%, onions: 2.5%, oranges, 1%, peaches: 2.5%, peanuts: 10%, pears: 1%, green peas (fresh & succulent): 30%, pecans: 10%, peppers (all): 20%, pistachios: 35%, pomegranate: 20%, potatoes: 10%, pummelo: 1%, pumpkins: 15%, soybeans: 5%, spinach: 2.5%, squash: 20%, strawberries: 55%, sweet corn: 40%, tangerines: 1%, tomatoes: 25%, walnuts: 15%, watermelons: 15%.

A default of 100% CT was used for all livestock and game commodities, freshwater finfish, and all other registered uses where no maximum/average %CT estimates were given by BEAD. All other commodities included for depicting FHE use were refined with the BEAD upper bound estimate of 4.65% for non-fumigant treatments made in FHEs (J. Becker, D413125, 10/07/2014).

5.4.3 Acute and Chronic Dietary Risk Assessment & Summary Tables

Highly refined acute probabilistic and refined chronic (average) dietary exposure and risk assessments were conducted for all existing uses of bifenthrin (D456242, D456221, and D456588, P. Savoia, 03/25/2020). 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

4.6% of the aPAD for the general U.S. population and 9.6% of the aPAD for all infants (< 1 year old), the most highly exposed population subgroup.

The chronic (food and drinking water) exposure assessment was conducted solely for the purposes of obtaining an average dietary exposure estimate for use in the aggregate assessment. The population subgroup with the highest average dietary exposure estimate is children 1-2 years old (0.000121 mg/kg/day).

Population Subgroup	Acute Assessment (99.9 th Percentile)			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	0.001439	4.6	NA	0.000076	NA
All infants	0.031	0.002976	9.6		0.000052	
Children 1-2 yrs*	0.031	0.002629	8.5		0.000121	
Children 3-5 yrs	0.031	0.002237	7.2		0.000093	
Children 6-12 yrs	0.031	0.001562	5.0		0.000056	
Youth 13-19 yrs	0.031	0.001088	3.5		0.000045	
Adults 20-49 yrs	0.031	0.001333	4.3		0.000086	
Adults 50-99 yrs	0.031	0.001206	3.9		0.000074	
Females 13-49 yrs	0.031	0.001097	3.5		0.000062	

*Most highly exposed population subgroup.

5.4.4 Cancer Dietary Risk Assessment

Bifenthrin is classified as a “possible human carcinogen.” Quantification of human cancer risk is not required. The acute reference dose (RfD) will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, which could result from exposure to bifenthrin.

6.0 Residential Exposure/Risk Characterization

There are existing residential uses that have been reassessed (since the 2017 assessment) in this document to incorporate the revised dermal POD, the submitted granular TTR study, and the reduced FQPA uncertainty factor from 3X to 1X for children less than 6 years old. 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.

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.1.

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.1. The algorithms used to estimate exposure and dose for residential handlers can be found in K. Rickard (D456241, 02/25/2020) and in the 2012 Residential SOPs⁸.

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 the same. A total 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 ARI is calculated as follows.

$$\text{Aggregate Risk Index (ARI)} = 1 \div [(\text{Dermal LOC} \div \text{Dermal MOE}) + (\text{Inhalation LOC} \div \text{Inhalation MOE})]$$

⁸ Available: <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>

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 (ARIs are greater than the LOC of 1).

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	140,000	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	94,000	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	15,000	2,000	39
	Hose-end Sprayer around gardens/trees	0.00117 lb ai/gallon	11 gallons	6.26	0.034	0.0010	0.0000055	160,000	64,000	660
	Hose-end Sprayer to turf	0.102 lb ai/acre	0.5 acres	6.26	0.034	0.0040	0.000022	41,000	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	200,000	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	100,000	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	50,000	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	34,000	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	25,000	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	20,000	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	17,000	250,000	97
	Shampoo to dogs ⁸ (Over 84 to 98 lbs)	2.3E-04 lb ai/pet	2 pets	2000	0.29	0.011	0.0000017	14,000	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	13,000	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	11,000	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	10,000	150,000	58	
Liquid Concentrate	Manually-pressurized handwand (w/ or w/o pin stream nozzle) to indoor environment [Broadcast,	0.0041 lb ai/gal	0.5 gallons	69	1.1	0.0018	0.00000028	93,000	12,000	240

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
	Perimeter/Spot/Bedbug]									
	Manually-pressurized handwand around gardens/trees	0.00521 lb ai/gallon	5 gallons	63	0.018	0.021	0.0000059	8,000	60,000	46
	Manually-pressurized handwand to turf	0.00521 lb ai/gallon	5 gallons	63	0.018	0.021	0.0000059	8,000	60,000	46
	Hose-end Sprayer around gardens/trees	0.00521 lb ai/gallon	11 gallons	58	0.0014	0.042	0.000001	3,900	350,000	23
	Hose-end Sprayer to turf	0.196 lb ai/acre	0.5 acres	13.4	0.022	0.016	0.000027	10,000	13,000	52
	Backpack around gardens/trees	0.00521 lb ai/gallon	5 gallons	130	0.14	0.042	0.000046	3,900	7,700	21
	Backpack to turf	0.00521 lb ai/gallon	5 gallons	130	0.14	0.042	0.000046	3,900	7,700	21
	Sprinkler can around gardens/trees	0.00521 lb ai/gallon	5 gallons	58	0.0014	0.019	0.0000046	8,700	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	19,000	24,000	97
	Sprinkler can to turf/ant mounds	0.10 lb ai/mound	5 mounds	13.4	0.022	0.084	0.00014	2,000	2,500	10
Granule	Push-type rotary spreader around gardens/trees	0.000012 lb ai/ft ²	1200 ft ²	0.81	0.0026	0.00015	0.00000047	1,100,000	750,000	7,700
	Push-type rotary spreader to turf	0.5 lb ai/acre	5 acres	0.81	0.0026	0.0025	0.0000081	65,000	43,000	450
	Belly grinder to turf	0.000012 lb ai/ft ²	1200 ft ²	360	0.039	0.065	0.000007	2,500	50,000	25
	Spoon around gardens/trees	0.000012 lb ai/ft ²	1200 ft ²	6.2	0.087	0.0011	0.000016	150,000	22,000	490
	Spoon to turf	0.000012 lb ai/ft ²	100 ft ²	6.2	0.087	0.000093	0.0000013	1,800,000	270,000	5,900
	Hand dispersal around gardens/trees	0.000012 lb ai/ft ²	1200 ft ²	160	0.38	0.029	0.000068	5,700	5,100	43
	Hand dispersal to turf	0.000012 lb ai/ft ²	100 ft ²	160	0.38	0.0024	0.0000057	68,000	61,000	510
	Cup around gardens/trees	0.000012 lb ai/ft ²	1200 ft ²	0.11	0.013	0.000020	0.0000023	8,300,000	150,000	4,700
	Cup to turf	0.000012 lb ai/ft ²	100 ft ²	0.11	0.013	0.0000017	0.00000002	99,000,000	1,800,000	56,000
	Spoon dispersal to turf/ant mounds	0.0000449 lb ai/mound	5 mounds	6.2	0.087	0.0000017	0.00000024	94,000,000	14,000,000	260,000
Dust	Shaker can to indoor surfaces/voids ^{10,11}	0.0000009 lb ai/ft ²	1200 ft ²	4300	18	0.058	0.00024	2,800	1,400	12
	Shaker can to gardens/trees	0.0000005 lb ai/ft ²	1200 ft ²	4300	18	0.032	0.00014	5,100	2,600	22

1 Based on registered labels [see Section 3.3 and Table F.1 (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 ft²) × Area Treated or Amount Handled (A/day, gallons/day, or ft²/day) ÷ Body Weight (80 kg).

4 Inhalation Dose = Inhalation Unit Exposure (mg/lb ai) × Application Rate (lb ai/acre, gal, or ft²) × Area Treated or Amount Handled (A/day, gallons/day, or ft²/day) ÷ Body Weight (80 kg).

5 Dermal MOE = Dermal NOAEL (163.7 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.

11 Residential handler assessment does not include use on stored products – EPA Reg. No. 1021-1858 does not include a maximum application rate for bifenthrin treatment of stored products, including treating pantries, shelves, and drawers. The use directions state “thoroughly treat floors, walls, and other surfaces” but a maximum rate is not provided. Residential handler assessment also does not include an assessment for dust application to treat carpet beetles because a maximum application rate was not provided. EPA Reg. no. 1021-1858 also allows use on lawns/turf but an application rate was not provided.

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.1). In addition, the exposure/risk assessment for residential post-application exposures also incorporates uses resulting from occupational handler application (Appendix F, Table F.3) 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, are considered negligible. The lifestages selected for each post-application scenario are based on an analysis provided as an Appendix in the 2012 Residential SOPs⁹. 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 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. For these same reasons, the episodic ingestion scenario is not recommended for inclusion in the aggregate assessment.

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

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

doses are detailed in the 2012 Residential SOPs⁹. 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 and granular formulations were also used. The assumptions used for the post-application residential assessment are summarized in Appendix G and in K. Rickard (D456241, 02/25/2020).

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

All of the residential post-application exposures did not result in risk estimates of concern, except the following scenarios:

Children (1 to < 2 years old):

High contact activities following liquid application to lawns/turf at an application rate of 2.3 lb ai/A (dermal MOE = 35, LOC = 100)

- Hand-to-mouth exposures following liquid application to lawns/turf at an application rate of 2.3 lb ai/A (MOE = 32, LOC = 100)
- Combined dermal and hand-to-mouth exposures following liquid application to lawns/turf at an application rate of 2.3 lb ai/A (MOE = 17, LOC = 100)
- Episodic granular ingestion following application to lawns/turf assuming maximum % ai in registered granular formulations of bifenthrin (0.2%) and ingestion rates adjusted for bifenthrin-specific application rates¹⁰ (acute/episodic ingestion MOE = 85, LOC = 100)

Adults:

- High contact activities following liquid application to lawns/turf at an application rate of 2.3 lb ai/A (dermal MOE = 69, LOC = 100)

PRD also requested HED evaluate a lower application rate of 0.23 lb ai/A for liquid/spray formulations of bifenthrin on residential turf since there may be some discrepancy with the current maximum labeled rate of 2.3 lb ai/A (PRD has noted that the registrant, FMC Corporation, has submitted a comment noting that the correct residential turf application rate for

¹⁰ The assumed ingestion rate for dry pesticide formulations (e.g., pellets and granules) is 0.3 gram/day for children 1 < 2 years old. It is assumed that if 150 pounds of product were to be applied to a ½ acre lawn, the amount of product per square foot would be approximately 3 g/ft² and a child would consume one-tenth of the product available in a square foot. This rate has been refined with product-specific information to reflect the amount of product applied on a per area basis (200 lb product applied per acre to result in an ingestion rate of 0.2 g/day).

liquid/spray should be 0.23 lb ai/A). There were no risk estimates of concern for adults and children from exposure following liquid applications of bifenthrin at a rate of 0.23 lb ai/A (all MOEs are greater than the LOC of 100).

Table 6.2. Residential Post-Application Non-Cancer Exposure and Risk Estimates for Bifenthrin.							
Lifestage	Post-Application Scenario	Deposited Residue (µg/cm ²) 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 = 100)	
Indoor Environments							
Indoor Spray - Perimeter/Spot/Bedbug (coarse)							
Adult	Carpet	Dermal	Deposited residue (ug/cm ²) = 2.6 for carpet/hard surfaces, 2.53 for mattress	0.035	4,600		
	Hard Surface			0.018	9,300		
	Mattress			0.011	15,000		
Child 1 to <2 years	Carpet	Dermal		0.034	4,800	X	
		Hand to Mouth		0.0051	610	X	
		Object to Mouth		0.00068	4,600		
	Mattress	Dermal		0.024	6,700	X	
	Hard Surfaces	Dermal		0.034	4,800	X	
		Hand to Mouth		0.0026	1,200	X	
Object to Mouth		0.00068		4,600			
	Mattress	Dermal	0.024	6,700	X		
Indoor Spray - Perimeter/Spot/Bedbug (Pin Stream)							
Adult	Carpet	Dermal	Deposited residue (ug/cm ²) = 1.5 for carpet/hard surfaces	0.02	8,000		
	Hard Surface			0.01	16,000		
Child 1 to <2 years	Carpet	Dermal		0.02	8,300	X	
		Hand to Mouth		0.0029	1,100	X	
		Object to Mouth		0.00039	7,900		
	Hard Surface	Dermal		0.02	8,300	X	
		Hand to Mouth		0.0015	2,100	X	
		Object to Mouth		0.00039	7,900		
Indoor Spray - Crack and Crevice							
Adult	Carpet	Dermal		Deposited residue (ug/cm ²) = 0.4	0.0054	30,000	
	Hard Surface		0.0027		60,000		
Child 1 to <2 years	Carpet	Dermal	0.0052		31,000	X	
		Hand to Mouth	0.00079		3,900	X	
		Object to Mouth	0.00010		30,000		
	Hard Surfaces	Dermal	0.0052		31,000	X	
		Hand to Mouth	0.00039		7,900	X	
		Object to Mouth	0.00010		30,000		
Lawns and Turf⁵							
Liquid Formulations							
Adult		Dermal	2.3 (TTR = 0.702)	2.37	69		

Table 6.2. Residential Post-Application Non-Cancer Exposure and Risk Estimates for Bifenthrin.							
Lifestage	Post-Application Scenario		Deposited Residue (µg/cm ²) 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 = 100)
	High Contact Lawn Activities		0.23 (TTR = 0.070)	0.237	690		
	Mowing Turf		2.3 (TTR = 0.702)	0.048	3,400		
	Golfing		0.23 (TTR = 0.070)	0.0048	34,000		
			0.2 (TTR = 0.061)	0.016	10,000		
Child 1 to <2 years	High Contact Lawn Activities	Dermal	2.3 (TTR = 0.702)	4.69	35	X	X (2.3 lb ai/A) = 17 XX (0.23 lb ai/A) = 170
			0.23 (TTR = 0.070)	0.469	350	XX	
	Lawns/Turf	Hand to Mouth	2.3 (TTR = 0.702)	0.096	32	X	
			0.23 (TTR = 0.070)	0.0096	320	XX	
		Object to Mouth	2.3 (TTR = 0.702)	0.0029	1,100		
			0.23 (TTR = 0.070)	0.00029	11,000		
		Soil ingestion	2.3 (TTR = 0.702)	0.000078	40,000		
			0.23 (TTR = 0.070)	0.0000078	400,000		
Child 6 to <11 years	Golfing	Dermal	0.2 lb ai/A	0.022			
Child 11 to <16 years	Mowing Turf	Dermal	2.3 lb ai/A	0.055			
	Golfing		0.2 lb ai/A	0.019			
Solid Formulations							
Adult	High Contact Lawn Activities	Dermal	0.5 (TTR = 0.0035)	0.013	12,000		
			0.2 (TTR = 0.0014)	0.0053	31,000		
	Mowing Turf		0.5 (TTR = 0.0035)	0.00024	680,000		
			0.2 (TTR = 0.0014)	0.00014	1,100,000		
	Golfing		0.4 (TTR = 0.0028)	0.00074	220,000		
			0.2 (TTR = 0.0014)	0.00037	440,000		
Children 1 to <2	High Contact Lawn Activities	Dermal	0.5 (TTR = 0.0035)	0.026	6,400	X	X (0.5 lb ai/A): 4,300 XX (0.2 lb ai/A): 11,000
			0.2 (TTR = 0.0014)	0.010	16,000	XX	
		Hand to Mouth	0.5 (TTR = 0.0035)	0.00024	13,000	X	
			0.2 (TTR = 0.0014)	0.00010	33,000	XX	
		Object to Mouth	0.5 (TTR = 0.0035)	0.000015	210,000		
			0.2 (TTR = 0.0014)	0.0000064	530,000		
		Soil ingestion	0.5 (TTR = 0.0035)	0.000017	180,000		
			0.2 (TTR = 0.0014)	0.00000068	460,000		
		Episodic Granule ingestion	0.2% ai (0.5 lb ai/A)	0.036	85		
			0.34 lb ai/A	0.031	100		
Child 6 to <11 years	Golfing	Dermal	0.4 (TTR = 0.0028)	0.0010	160,000		
			0.2 (TTR = 0.0014)	0.00051	320,000		
Child 11 to <16 years	Mowing	Dermal	0.5 (TTR = 0.0035)	0.00024	680,000		
			0.2 (TTR = 0.0014)	0.00017	990,000		
	Golfing		0.4 (TTR = 0.0028)	0.00086	190,000		
			0.2 (TTR = 0.0014)	0.00043	380,000		
Garden and Trees							
Liquid Formulations							
Adult	Gardens	Dermal	0.23 (DFR = 0.618)	0.143	1,100		
	Trees		0.23 (DFR = 0.618)	0.013	12,000		
	Indoor plants		0.23 (DFR = 0.618)	0.0017	96,000		
Child 6 to <11 years	Gardens		0.23 (DFR = 0.618)	0.098	1,700		
	Trees		0.23 (DFR = 0.618)	0.009	18,000		
	Indoor plants		0.23 (DFR = 0.618)	0.0012	140,000		

Table 6.2. Residential Post-Application Non-Cancer Exposure and Risk Estimates for Bifenthrin.						
Lifestage	Post-Application Scenario	Deposited Residue (µg/cm ²) 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 = 100)
Solid Formulations						
Adult	Gardens	Dermal	0.5 (DFR = 1.34)	0.310	530	
	Trees		0.5 (DFR = 1.34))	0.029	5,700	
	Indoor Plants		0.5 (DFR = 1.34)	0.0037	44,000	
Child 6 to <11 years	Gardens	Dermal	0.5 (DFR = 1.34)	0.212	770	
	Trees		0.5 (DFR = 1.34)	0.0195	8,400	
	Indoor Plants		0.5 (DFR = 1.34)	0.0025	65,000	
Treated Pets (Dogs Treated with Shampoos)						
Adult	Dogs (Up to 7 lb)	Dermal	7.4 mg ai	0.0032	51,000	
	Dogs (Over 7 to 14 lbs)	Dermal	14.8 mg ai	0.0064	26,000	
	Dogs (Over 14 to 28 lbs)	Dermal	29.6 mg ai	0.0081	20,000	
	Dogs (Over 28 to 42 lbs)	Dermal	44.4 mg ai	0.0078	21,000	
	Dogs (Over 42 to 56 lbs)	Dermal	59.1 mg ai	0.0079	21,000	
	Dogs (Over 56 to 70 lbs)	Dermal	73.9 mg ai	0.0082	20,000	
	Dogs (Over 70 to 84 lbs)	Dermal	88.7 mg ai	0.0086	19,000	
	Dogs (Over 84 to 98 lbs)	Dermal	103.5 mg ai	0.0089	18,000	
	Dogs (Over 98 to 112 lbs)	Dermal	118.3 mg ai	0.0092	18,000	
	Dogs (Over 112 to 126 lbs)	Dermal	133.1 mg ai	0.0095	17,000	
	Dogs (Over 126 to 140 lbs)	Dermal	147.9 mg ai	0.0097	17,000	
Child (1 < 2 yrs)	Dogs (Up to 7 lb)	Dermal	7.4 mg ai	0.0011	150,000	
	Dogs (Over 7 to 14 lbs)	Dermal	14.8 mg ai	0.0022	74,000	
	Dogs (Over 14 to 28 lbs)	Dermal	29.6 mg ai	0.0028	58,000	
	Dogs (Over 28 to 42 lbs)	Dermal	44.4 mg ai	0.0027	60,000	
	Dogs (Over 42 to 56 lbs)	Dermal	59.1 mg ai	0.0028	59,000	
	Dogs (Over 56 to 70 lbs)	Dermal	73.9 mg ai	0.0029	57,000	
	Dogs (Over 70 to 84 lbs)	Dermal	88.7 mg ai	0.0030	55,000	
	Dogs (Over 84 to 98 lbs)	Dermal	103.5 mg ai	0.0031	53,000	
	Dogs (Over 98 to 112 lbs)	Dermal	118.3 mg ai	0.0032	51,000	
	Dogs (Over 112 to 126 lbs)	Dermal	133.1 mg ai	0.0033	50,000	
	Dogs (Over 126 to 140 lbs)	Dermal	147.9 mg ai	0.0034	48,000	X
	Dogs (Up to 7 lb)	Hand to Mouth	7.4 mg ai	0.000081	38,000	

9,900

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

Lifestage	Post-Application Scenario		Deposited Residue ($\mu\text{g}/\text{cm}^2$) 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 = 100)
	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 = 163.7 mg/kg/day and incidental oral/acute dietary (episodic granular ingestion) POD = 3.1 mg/kg/day.

4 Combined MOE = $1 \div [1/(\text{Dermal MOE}) + (1/\text{Incidental Oral MOE})]$.

5 For lawns/turf, application rates derived from EPA Reg. No. 279-3152 (Liquid), EPA Reg. No. 279-3343 (Granular for all use sites except golf courses) and 279-9547 (Granular for golf courses).

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. In addition, because of a possible discrepancy in the label rates, scenarios involving exposure resulting from performing high contact activities on treated turf assuming a lower maximum application rate of 0.23 lb ai/A for liquid/spray formulations of bifenthrin on residential turf were also 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.

Lifestage	Exposure Scenario	Dose (mg/kg/day) ¹				MOE ²				
		Dermal	Inhalation	Oral	Total	Dermal (LOC = 100)	Inhalation (LOC = 30) ³	Oral (LOC = 100)	Total (LOC = 100)	
Adults	Post-Application Exposure from Treated Turf (Liquid Formulations at 0.23 lb ai/A)	0.237	N/A	N/A	0.237	690	N/A	N/A	690	
	Post-Application Exposure from Treated Gardens (Granular Formulations)	0.310		N/A	0.310	530		N/A	530	
Children 1 to < 2 years old	Post-Application Exposure from High Contact Lawn Activities (Liquid Formulations at 0.23 lb ai/A)	0.469		0.0096	0.4786	350		N/A	320	170
	Post-Application Exposure from treated Carpet	0.034		0.0051	0.0391	4,800			610	500
	Post-Application Exposure from treated Mattress	0.024		N/A	0.024	6,700			N/A	
Children 6 to < 11 years old	Post-Application Exposure to Treated Gardens	0.098		N/A	0.0977	1,700		N/A	N/A	1,700
Children 11 to 16 years old	Post-Application Exposure from Golfing on Treated Turf	0.019			0.019	8,700				8,700

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 = $1 \div [1/(\text{Dermal MOE}) + (1/\text{Incidental Oral MOE})]$.

3 Residential handler dermal + inhalation risks were not recommended for inclusion in the adult aggregate risk assessment because dermal post-application risk estimates provided higher exposure estimates.

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 are 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 and is equivalent to the acute dietary assessment. There are no acute aggregate risk estimates of concern (see Section 5.4.3).

7.2 Short-Term Aggregate Risk

In estimating the short-term aggregate risk for bifenthrin, HED has aggregated the short-term residential exposure (Table 6.3) and average dietary (food and water) exposure (Table 5.4.3) for adults and children. The following residential exposure scenarios selected for aggregation represent the worst-case risk estimates of the residential scenarios that were determined not to be of concern:

- Adults contacting treated gardens (dermal exposure).
- Children 1 to < 2 years old contacting treated carpets and mattresses (e.g., after bedbug treatments). If a product is registered 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 treated carpets were combined with dermal exposures from contacting treated mattresses.
- Children 6 to < 11 years old contacting treated gardens (dermal exposure).
- Children 11 to 16 years old golfing on treated turf (dermal exposure).

Residential exposures that were of concern [i.e., high contact activities on treated turf for adults and children at maximum labeled rates for liquid formulations (2.3 lb ai/A)] were not aggregated because the additional exposure from food and water would only increase the risk estimates. However, because of a possible discrepancy in the label rates, an aggregate assessment was performed for adults and children (1 to < 2 years old) performing high contact activities on treated turf assuming a lower maximum application rate of 0.23 lb ai/A for liquid/spray formulations of bifenthrin on residential turf.

The short-term aggregate (food, drinking water, and residential exposures) assessment for adults resulted in MOEs of 1,100 (treated gardens) and 520 (treated turf at 0.23 lbs ai/A) (LOC = 100). The short-term aggregate assessment for children 1 to < 2 years old resulted in MOEs of 490 (treated carpets/mattresses) and 170 (treated turf at 0.23 lbs ai/A) (LOC = 100). The short-term aggregate assessment for children 6 to < 11 years old and children 11 to 16 years old resulted in MOEs of 1,600 (treated gardens) and 7,700 (golfing), respectively (LOC = 100). There are no short-term aggregate risk estimates for the scenarios assessed.

Population	Dietary Exposure		Dermal Residential Exposure		Oral Residential Exposure		Aggregate MOE ⁴ (LOC = 100)
	mg/kg/day	MOE ¹	mg/kg/day	MOE ²	mg/kg/day	MOE ³	
Adults (Treated Gardens)	0.000086	36,000	0.310	530	N/A	N/A	520
Adults (High Contact Lawn Activities w/Liquid Formulations at 0.23 lb ai/A)	0.000086	36,000	0.237	690	N/A	N/A	680
Children 1 to < 2 years old (Treated Carpets/Mattresses)	0.000121	26,000	0.058	2,800	0.0051	610	490

Population	Dietary Exposure		Dermal Residential Exposure		Oral Residential Exposure		Aggregate MOE ⁴ (LOC = 100)
	mg/kg/day	MOE ¹	mg/kg/day	MOE ²	mg/kg/day	MOE ³	
Children 1 to < 2 years old (High Contact Lawn Activities w/Liquid Formulations at 0.23 lb ai/A)	0.000121	26,000	0.469	350	0.0096	320	170
Children 6 to < 11 years old (Treated Gardens)	0.000056	55,000	0.098	1,700	N/A	N/A	1,600
Children 11 to 16 years old (Golfing on Treated Turf)	0.000045	69,000	0.019	8,700	N/A	N/A	7,700

1 MOE dietary = [(BMDL_{1SD} = 3.1 mg/kg)/(chronic dietary exposure)]. The adult dietary exposure used is for the population subgroup "Adults 20-49 years old" and is the highest exposure for any of the adult-only subgroups (Table 5.4.3). The children dietary exposure used in the bifenthrin aggregate assessment is that for "Children 1-2 years old", "Children 6-12 years old" and "Youth 13-19 years old" (Table 5.4.3). The lifestages selected for each residential post-application scenario are based on an analysis provided as an Appendix in the 2012 Residential SOPs. This analysis provides a quantitative and qualitative basis for the representative lifestage for most residential post-application scenarios involving young children, as well as reasons why a residential assessment is not conducted for infants. For children, therefore, the bifenthrin aggregate assessment only combines the residential exposure estimates for children 1 to <2 years old, children 6 to <11 years old and, children 11 to <16 years old with the average dietary exposure estimates for the most similar lifestages (Children 1-2 years old, Children 6-12 years old and Youth 13-19 years old).

2 MOE dermal = [(BMDL₁₀ = 163.7 mg/kg)/(dermal residential exposure)]. See Table 6.3.

3 MOE oral = [(BMDL_{1SD} = 3.1 mg/kg)/(hand-to-mouth residential exposure)]. See Table 6.3.

4 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." Quantification of human cancer risk is not required. The acute reference dose (RfD) will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, which could result from exposure to bifenthrin.

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

A quantitative spray drift assessment was conducted for 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 at the 2.3 lb ai/A rate; therefore, they cannot be considered protective of potential spray drift exposures.

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.¹¹ 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 simazine. 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)*.

¹¹ This approach is consistent with the requirements of the EPA's Worker Protection Standard.

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.^{12,13} 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). 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).¹⁴

In addition to the screening level spray drift scenarios described above, additional results are provided in Appendix D (spreadsheets) in D456241 (K. Rickard, 02/25/2020) 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).

¹²<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#AgDrift>

¹³ Note that for many cases the scenarios outlined in the screening approach represent actual use practice so risk assessors should be aware and characterize these appropriately.

¹⁴ 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.

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 100. 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 or children 1 to < 2 years old 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 are all greater than 1,500 at the field edge (LOC = 100). There were no combined dermal and incidental oral risk estimates of concern at the field edge for children 1 to < 2 years old, assuming the maximum registered application rates and assuming screening-level droplet sizes and boom heights (MOEs \geq 100). The combined dermal and incidental oral MOEs for children 1 to < 2 years old are all greater than 380 at the field edge (LOC = 100).

Crop	Application rate (lb ai/A)	Distance From Field Edge (Feet)	Adult Dermal MOEs ²			Children 1 < 2 years old Combined Dermal + Incidental Oral MOEs ²		
			LOC = 100			LOC = 100		
			Aerial	Groundboom	Airblast	Aerial	Groundboom	Airblast
Citrus	0.5	0	N/A	1,700	N/A	N/A	410	N/A
Tobacco	0.40	0	1,500	2,100	2,800	380	520	670
Max rate for all other crops	0.30	0	2,100	2,800	3,700	500	690	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. "N/A" provided when equipment not applicable based on the use pattern.

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 new pyrethroid and pyrethrin use, the Agency has conducted a screen to evaluate any potential impacts on the CRA prior to registration of that use. A new turf use for the pyrethroid, tau-fluvalinate, was assessed after completion of the cumulative, which did impact the worst-case non-dietary risk estimates identified in the 2011 CRA for the turf scenario (Memo, DeLeon, H., D450820, 12/16/2019). However, the overall finding (i.e., that the pyrethroid cumulative risk is below the Agency's level of concern) did not change upon registration of this new use.

Prior to a final registration review decision for bifenthrin, the Agency will determine whether the 2011 CRA needs to be updated based on the availability of any new hazard, use, or exposure information that could potentially change the conclusions of or otherwise impact the 2011 CRA.

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.2 and F.3). 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.2. and Table F.3). The maximum single application rate for each crop scenario was assessed based on 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,¹⁵” 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 website¹⁶.

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 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) document¹⁷). 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

¹⁵ Available: <https://www.epa.gov/sites/production/files/2016-11/documents/handler-exposure-table-2016.pdf>

¹⁶ Available: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>

¹⁷ <http://archive.epa.gov/pesticides/reregistration/web/pdf/0063fact.pdf>

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 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.

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 D456241 (K. Rickard, 02/25/2020).

Combining Exposures/Risk Estimates:

A total 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 ARI is calculated as follows.

$$\text{Aggregate Risk Index (ARI)} = 1 \div [(\text{Dermal LOC} \div \text{Dermal MOE}) + (\text{Inhalation LOC} \div \text{Inhalation MOE})]$$

Summary of Occupational Handler Non-Cancer Exposure and Risk Estimates

The majority of the occupational handler dermal, inhalation, and combined (dermal + inhalation) risk estimates were not of concern (dermal MOEs \geq 100, inhalation MOEs \geq 30, and ARI \geq 1) with baseline attire for the registered uses of bifenthrin. For those scenarios that were of concern with baseline attire, additional PPE was assessed. A summary of the occupational handler exposure and risk estimates is provided in Appendix D. The scenarios that result in risk estimates of concern with baseline attire are as follows:

- Mixing/Loading liquids for aerial ultra-low volume (ULV) application to cotton (0.1 lb ai/A):
 - Baseline: Dermal **MOE = 79**, Inhalation MOE = 510, **ARI = 0.75**
 - Baseline + gloves: Dermal MOE = 460, Inhalation MOE = 510, ARI = 3.6.

Waterproof or chemical resistant gloves are 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 = **72**, Inhalation MOE = 320, ARI = **0.67**
 - Baseline + gloves: Dermal MOE = 210, Inhalation MOE = 320, ARI = 1.8.
Waterproof or chemical resistant gloves are required by the representative labels evaluated (EPA Reg. Nos. 279-3313 and 279-3302).

HED has no data to assess exposures to pilots using open cockpits. The only data available is for exposure during aerial applications (covering both airplanes and helicopters) of liquid formulations to pilots in enclosed cockpits (data from AHETF) and of granule formulations in enclosed cockpits (data from PHED). Therefore, risks to pilots are assessed using the engineering control (enclosed cockpits) and baseline attire (long-sleeve shirt, long pants, shoes, and socks); use of the data in this fashion is consistent with the Agency's Worker Protection Standard (WPS) stipulations for engineering controls, which says label-required PPE for applicators can be reduced when using an enclosed cockpit (40 CFR 170.240(d)(6)(iii)) as well as a provision regarding use of gloves for aerial applications (40 CFR 170.240(d)(6)(i)), which says 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 Agricultural Handler Exposure Task Force (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 3¹⁸ which, along with additional information about the ARTF data, can be found at the Agency website¹⁹. Only the maximum/highest TCs were presented for each scenario.

Application Rate: The registered application rates for bifenthrin are listed in Appendix F.

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

Dislodgeable Foliar Residues: As noted in K. Rickard (D456241, 02/25/2020), a total of four chemical-specific DFR data sets have been submitted for bifenthrin for the following crops: cotton (MRID 42142201), roses and chrysanthemums (MRID 44955201), and strawberries (MRID 44684401). The cotton DFR data was found to be unacceptable for risk assessment due

¹⁸ Available: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>

¹⁹ Available: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>

to quality assurance (QA)/quality control (QC) concerns (see Appendix G and K. Rickard, D456241, 02/25/2020). The chrysanthemum and strawberry data were used in the occupational post-application assessment.

Turf Transferrable Residues: As noted in the residential post-application section, liquid and granular TTR studies are available for bifenthrin (MRID 44955201 and 50544404), and these data were used in the occupational post-application assessment.

Occupational Post-Application Non-Cancer Dermal Risk Estimates

Using chemical-specific DFR and TTR data, the occupational dermal post-application MOEs are not of concern (MOEs ≥ 100) for the registered uses of bifenthrin. The occupational post-application MOEs representing the worst-case activity scenario for each crop range from 320 to 320,000 (LOC = 100). 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 III for acute eye irritation potential and Toxicity Category IV for 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 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 I 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

- Anand, M., Bruckner, W., Haines, W., Muralidhara, S., Fisher, J., Padilla, S. (2006). Characterization of deltamethrin metabolism by rat plasma and liver microsomes. *Toxicol Appl Pharmacol* 212(2):156-166.
- Backus, B, Rinde, E. (04/29/1992) TXR 0051809. Third Carcinogenicity Peer Review of Bifenthrin.
- Becker, J. (10/07/2014). D413125. Upper Bound Estimate of the Likelihood of Insecticide Residues on Food Resulting from Treatment in Food Handling Establishments (D413125).
- Breckenridge, C., Holden, L., Sturgess, N., Weiner, M., Sheets, L., Sargent, D., Soderlund, D., Choi, J., Symington, S., Clark, J., Burr, S., Ray, D. (2009). Evidence for a Separate Mechanism of Toxicity for the Type I and Type II Pyrethroid Insecticides. *Neurotoxicology*. Suppl 1:S17-31.
- Flood, M. (07/27/1993). The Metabolism Committee Meeting Held on July 27, 1993. Plant and Animal Metabolism of Bifenthrin.
- Crofton K., Kehn, L., Gilbert, M. (1995). Vehicle and Route Dependent Effects of a Pyrethroid Insecticide, Deltamethrin, on Motor Function in the Rat. *Neurotoxicology and Teratology*. 17:489-495.
- Godin, S., Dvito, M., Hughes, M., Gross, D., Starr, J., Setzer, R., Conolly, R., Tornero-Velez, R., Scollon, E., (2010) Physiologically Based Pharmacokinetic Modeling of Deltamethrin: Development of a Rat and Human Diffusion-Limited Model. *Toxicological Sciences*. Society of Toxicology. 115(2):330-343.
- Habiba, U. (08/12/2013). TXR 0056729. SYNTHETIC PYRETHROIDS: Summary of Hazard and Science Policy Council (HASPOC) Meeting on July 25, 2013: Recommendations on Data Requirement for Immunotoxicity Studies for Synthetic Pyrethroid Pesticides.
- Habiba, U. (11/13/2013). TXR 0056830. SYNTHETIC PYRETHROIDS: Update to the August 12, 2013 Hazard and Science Policy Council (HASPOC) Memo: Recommendations on Data Requirement for Immunotoxicity Studies for Synthetic Pyrethroid Pesticides.
- Hoppin, J., Umbach, D., Long, S., London, S., Henneberger, P., Blair, A., Alvanja, M., Freeman, L., Sandler, D. (2017). Pesticides are Associated with Allergic and Non-Allergic Wheeze Among Male Farmers. *Environmental Health Perspectives*. 125(4):535-543.
- Lawrence, L., Caida, J. (1982). Pyrethroid Toxicology Mouse Intracerebral Structure Toxicity Relationships. *Pesticide Biochemistry and Physiology*. 18(1): 9-14.
- Lenners, A. (2019). PC Code 128825. Updated Screening Level Usage Analysis (SLUA) Report for Bifenthrin PC# (128825).

Lenners, A., and Mallampalli, N. (2020). Bifenthrin Usage Analysis in Support of Human Health Risk Assessment for Registration Review (Revised).

Leshin, J. (01/07/2015). TXR 0057021. Bifenthrin: Summary of Hazard and Science Policy Committee (HASPOC) Meetings of July 31, 2014: Re-evaluation on the need for an acute inhalation toxicity.

Levy, S. and Kramer, G. (08/15/2002). D279905. Bifenthrin in Food Handling Establishments. Evaluation of Residue Data and Analytical Methods. MRID 45501801.

Mirfazaelian, A., Kim, K., Anand, S., Kim, H., Tornero-Velez, R., Bruckner, J., Fisher, J. (2006). Development of a Physiologically Based Pharmacokinetic Model for Deltamethrin in the Adult Male Sprague-Dawley Rat. *Toxicological Sciences*. 93(2): 432-442.

Recore, S. (07/26/2017). D441154. Bifenthrin: Updated Tier I Review of Human Incidents and Epidemiology for Draft Risk Assessment.

Rickard, K. (09/08/2016). D435062. Bifenthrin. Section 18 Request for Use on Pomegranate in California.

Rickard, K. (02/25/2020). D456241. Bifenthrin. REVISED Occupational and Residential Exposure and Risk Assessment for Registration Review.

Ruge, Z. (07/12/2019). D453185. Bifenthrin. Drinking Water Assessment (DWA) for the Proposed New Use on Sunflower Crop Subgroup 20B.

Savoia, P. (03/25/2020). D456242, D456221, and D456588. Bifenthrin. Acute and Chronic Dietary Exposure and Risk Assessments of Food and Drinking Water for Bifenthrin to Support Registration Review, PP#8F8704 Proposed Section 3 Registration on Sunflower Subgroup 20B, as well as PP#6E8482 Proposed Section 3 Registration on Pome Fruit Group 11-10 (except Mayhaw), Peach Subgroup 12-12B, Avocado, Pomegranate, Brassica Leafy Greens Subgroup 4-16B Treated at a 1-day PHI, and the Crop Group Expansions of Tomato to Tomato Subgroup 8-10A, Pepper to Pepper/Eggplant Subgroup 8-10B, Grape to Small Vine Climbing Fruit Except Fuzzy Kiwifruit Subgroup 13-07F, and Strawberry to Low Growing Berry Subgroup 13-07G.

Scollon, E. (06/27/2011). D381210, TXR 0056045. Re-Evaluation of the FQPA Safety Factor for Pyrethroid Pesticides

Shafer, T., Meyer, D., and Crofton, K. (2005). Developmental neurotoxicity of pyrethroid Insecticides: Critical Review and Future Research Needs. *Environmental Health Perspectives*. 113(2): 123–136.

Sheets, L., Doherty, J., Law, M., Reiter, L., Crofton, K. (1994). Age-Dependent Differences in the Susceptibility of Rats to Deltamethrin. *Toxicol Appl Pharmacol*. (126):186-190.

Smegal, D. (04/26/2012). TXR 0056209. Bifenthrin: Summary of Hazard and Science Policy Council (HASPOC) Meetings of January 4, 2012, March 8, 2012, and April 26, 2012: Recommendations on the need for sub-chronic inhalation and 90-day dermal toxicity studies.

Soderlund, D., J. Clark, L. Sheets, L. Mullin, V. Piccirillo, D. Sargent, J. Stevens and M. Weiner. (2002). Mechanisms of pyrethroid neurotoxicity: Implications for cumulative risk assessment. *Toxicology*. 171(1): 3 - 59.

Tan, J., and Soderlund, D, Human and rat [Nav1.3](#) voltage-gated sodium channels differ in inactivation properties and sensitivity to the pyrethroid insecticide tefluthrin. *Neurotoxicology*. January 1, 2009; 30 (1): 81-9.

Verscholye, R., Aldridge, W. (1980). Structure Activity Relationships of Some Pyrethroids in Rats. *Archives of Toxicology*. 45(4): 325-9.

Weiner, M., Nemec, M., Sheets, L., Sargent, D., Breckenridge, C. (2009). Comparative functional observational battery study of twelve commercial pyrethroid insecticides in male rats following acute oral exposure. *NeuroToxicology (30S):S1–S16*.

Wolanksy, M., C. Gennings, and K. Crofton. (2006). Relative potency for acute effects of pyrethroids on motor function in rats. *Toxicological Sciences*. 89 (1): 271-277.
http://www.latomeq.qb.fcen.uba.ar/imagenes/Wolansky_et_al_Pyrethroid_RPFs_Tox%20Sci_2006.pdf

Wolansky, M., McDaniel, K., Moser, V., Crofton, K. (2007). Influence of dosing volume on neurotoxicity of bifenthrin. *Neurotoxicology and Teratology*. (29):377-384.
<http://www.sciencedirect.com/science/article/pii/S0892036207000104>

Wolansky, M., and Harrill, J. (2008). Neurobehavioral Toxicology of Pyrethroid Insecticides in Adult Animals: A Critical Review. *Neurotoxicol Teratol*. 30(2):55-78.

Wolansky, M., Gennings, C., DeVito, M., Crofton, K. (2009). Evidence for Additive Effects of Pyrethroids on Motor Activity in Rats". *Environ Health Persp*. 117(10):1563-1570.

Whitby, K. (10/04/2011). D394576. Pyrethroid cumulative risk assessment.

Wolanksy, M., C. Gennings, and K. Crofton. 2006. Relative potency for acute effects of pyrethroids on motor function in rats. *Toxicological Sciences*. 89 (1): 271-277.

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.

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	NA 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	NA

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

Guideline No.	Study Type	MRID No.	Results	Toxicity Category
870.1100	Acute oral (rat)	47902604	LD ₅₀ = 58.4 mg/kg (M) LD ₅₀ = 43.0 mg/kg (F)	I
870.1200	Acute dermal (rat)	00132520	LD ₅₀ > 2,000 mg/kg (M & F)	III
870.1300	Acute inhalation (rat)	46008101	LC ₅₀ = 1.10 mg/L (M) LC ₅₀ = 0.8 mg/L (F) LC ₅₀ = 1.01 mg/L (C) Heated to 100° C for testing	III
870.2400	Primary eye irritation (rabbit)	46821102	Moderate irritant	III
		46029704	Conjunctivitis in 3/3 eyes resolving by day 4	III
870.2500	Primary skin irritation (rat)	00132521	Non-irritant	IV
870.2600	Dermal sensitization (guinea pig) (Maximization Test)	45924801	Dermal Sensitizer	N/A

Guideline No.	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

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
870.3150	00141200	90-Day Oral Toxicity - Dog (1984)	NOAEL = 2.21 mg/kg/day (males and females) 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	<u>Maternal Toxicity</u> NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. <u>Developmental Toxicity</u> NOAEL = not determined (fetuses not examined) LOAEL = not determined (fetuses not examined) Classification: Acceptable-Guideline
870.3700	00141201	Developmental Toxicity (Gavage) - Rat (1984)	<u>Maternal Toxicity</u> NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. <u>Developmental Toxicity</u> NOAEL = 1.77 mg/kg/day LOAEL = Not Observed Classification: Acceptable-Guideline
870.3700	45352301	Developmental Toxicity (Dietary) - Rat (2001)	<u>Maternal Toxicity</u> 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. <u>Developmental Toxicity</u> NOAEL = 15.5 mg/kg/day LOAEL = not observed. Classification: Acceptable-Guideline
870.3700	00145997	Developmental Toxicity - Rabbit (1984)	<u>Maternal Toxicity</u> NOAEL = 2.36 mg/kg/day LOAEL = 3.5 mg/kg/day based on treatment-related head and forelimb twitching. <u>Developmental Toxicity</u> NOAEL = greater than 7 mg/kg/day LOAEL = not observed Classification: Acceptable-Guideline

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
Reproductive Toxicity			
870.3800	00157225	Multigeneration Reproductive Toxicity - Rat (1986)	<p><u>Parental/Systemic Toxicity</u> 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.</p> <p><u>Reproductive/offspring Toxicity</u> NOAEL = 5.0 mg/kg/day. LOAEL = not observed.</p> <p>Classification: Acceptable-Guideline</p>
Chronic Toxicity/Carcinogenicity			
870.4100	00163065	Chronic Toxicity (1 Year) - Dog (1985)	<p>NOAEL = 1.3 mg/kg/day (males and females) LOAEL = 2.7 mg/kg/day (males and females) based on increased incidence of tremors.</p> <p>Classification: Acceptable-Guideline</p>
870.4300	00157226	Combined Chronic Toxicity/Carcinogenicity - Rat (1986)	<p>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.</p> <p>Carcinogenicity - No conclusive evidence of carcinogenic potential.</p> <p>Classification: Acceptable-Guideline</p>
870.4200	00157227	Carcinogenicity - Mice (1986)	<p>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.</p> <p>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.</p> <p>Classification: Acceptable-Guideline</p>
Neurotoxicity			
870.6200a	44862102	Acute Neurotoxicity - Rat	<p>NOAEL = 35 mg/kg (32.8 mg ai/kg/day).</p> <p>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.</p> <p>Classification: Acceptable-Guideline</p>

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
870.6200b	44862103	Sub-chronic Neurotoxicity - Rat	<p>NOAEL = 50 ppm (equivalent to 2.9 mg/kg/day in males and 3.7 mg/kg/day in females).</p> <p>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).</p> <p>Classification: Acceptable-Guideline</p>
870.6300	46750501	Developmental Neurotoxicity - Rat	<p>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).</p> <p>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).</p>
Dermal Toxicity			
870.3200	00141198	Dermal Toxicity - Rabbit	<p>NOAEL = 88 mg ai/kg/day (males and females)</p> <p>LOAEL = 442 mg ai/kg/day (males and females), based on loss of muscle coordination and increased incidence of tremors.</p>
870.3200	45280501	Dermal Toxicity - Rat	<p>NOAEL = 47 mg ai/kg/day (males and females) BMDL₁₀=96.3 mg/kg/day</p> <p>LOAEL = 93 mg ai/kg/day (males and females), based on staggered gait (M) and exaggerated hind limb flexion (F) BMD₁₀=187.0 mg/kg/day, based on exaggerated hind limb flexion</p>
Inhalation Toxicity			
870.3465	49462201	Inhalation toxicity - rat	<p>LOAEL = 0.0196 mg/L/day based on increased tremors and increased respiration rate</p> <p>NOAEL = 0.0059 mg/L/day</p>

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
Metabolism and Pharmacokinetics			
870.7485	00163067 40415102	Metabolism - Rat	<p>Very little of the administered radioactive dose was expired as ¹⁴C-CO₂ (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 ¹⁴C- 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.</p> <p>Classification: Acceptable-Guideline</p>
870.7485	00163069	Metabolism - Rat	<p>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 ¹⁴C-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.</p> <p>Classification: Acceptable-Guideline</p>
870.7485	00163070	Metabolism - Rat	<p>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.</p> <p>Classification: Acceptable-Guideline</p>

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
870.7485	00163071	Metabolism - Rat	<p>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.</p> <p>Classification: Acceptable-Guideline</p>
870.7485	00163066	Metabolism - Rat	<p>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.</p> <p>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.</p>
870.7485	40415100	Metabolism - Rat	<p>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.</p> <p>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.</p>

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
870.7485	00163068	Metabolism - Rat	<p>The results of the study demonstrated that the majority of radioactivity excreted in the feces was the parent compound and its intact hydroxylated metabolites. Much of the radioactivity excreted in urine was hydrolytic and hydrolytic/oxidative degradation products of the parent compound.</p> <p>Classification: Unacceptable-Guideline.</p>
Dermal Penetration			
Non-guideline	50981601		<p>In an <i>in vitro</i> dermal absorption study (Hughes and Edwards, 2010; MRID 50981601), ³H(G)]-bifenthrin was applied to human and rat epidermal membranes in static diffusion cells. Four separate studies were performed: a 24-h time course study; a 48-h time course study; a tape strip study; and a skin metabolism study. For rat skin discs, radioactivity was detected in the receptor fluid at the first (4 h) time point. After 24 h, 1.3-1.6% of the applied doses was detected in the receptor fluid, increasing to approximately 2% at 48 h. The skin retained 32.9-42.6%, with a greater (p<0.05) percentage found at 10 nmol than at 100 nmol. Tape stripping (ten strips) at 100 nmol removed 24.4%, with 19.5% remaining in the skin. The skin wash removed 59.4-68.8% of the applied doses, with a greater (p<0.05) percentage removed at 100 nmol compared to 10 nmol. Maximal flux ranged from 6.1-56.0 µg/cm²/h at 4 h, increasing with increasing dose. Only parent bifenthrin was detected in the rat skin extracts. For human skin discs, radioactivity was detected in the receptor fluid at 4 h. After 24 h, 1.0-1.2% of the applied doses was detected in the receptor fluid; for 24-48 h, the increase was 0.6% to 1%. The skin retained 13.8-20.7%, with a greater (p<0.05) percentage found at 10 nmol than at 100 nmol. Tape stripping removed 19.8%, with 5.4% remaining in the skin. The skin wash removed 75.4-82.6% of the applied doses. Maximal flux ranged from 4.7-38.0 µg/cm²/h at 4 h, increasing with dose.</p>

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
870.7600	41917503	Dermal Penetration - Rats	<p>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.</p> <p>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.</p>
870.7600	41917502	Dermal Penetration - Rats	<p>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%.</p> <p>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.</p>
870.7600	00163072	Dermal Penetration - Rats	<p>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. 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 %.</p>

Table A.2.2. Toxicity Profiles for Bifenthrin.			
Guideline No.	MRID No.	Study Type	Results
			<p>Classification: This dermal absorption study is classified as acceptable. However, by itself, <u>does not</u> 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.</p>
870.7600	41284202	Dermal Penetration - Rats	<p>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.</p> <p>This dermal absorption study is classified as acceptable. However, because only one dose was used, this study, by itself, <u>does not</u> 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.</p>

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

Interval Limit	Variable	Estimate	Std. Err.	95.0% Wald Confidence	
				Lower Conf. Limit	Upper Conf.
	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

Dose	Est._Prob.	Expected	Observed	Size	Scaled 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

Parameter	Value	Reference
Melting point/range	68-70.6 °C	Product Chemistry Chapter of TRED (S. Levy, D283808, 08/21/2002), except where noted.
pH	NA	
Density	1.26 g/mL (24 °C; true particle density)	
Water solubility	0.014 ug/L ¹	
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 x 10 ⁻⁵ (25 °C)	
Dissociation constant, pK _a	NA	
Octanol/water partition coefficient, Log(K _{ow})	>1 x 10 ⁶	
UV/visible absorption spectrum	NA	

¹ EFED memo J. Meléndez, D434407, 01/19/2017.

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 website²⁰.

²⁰ <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.										
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	44,000	0.00074	1,400	42
	Field crop, high-acreage	0.1 lb ai/acre	1200 acres	8.4	1.7	0.013	13,000	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	49,000	0.00068	1,500	45
	Field crop, typical	0.3 lb ai/acre	80 acres	8.4	1.7	0.0025	65,000	0.00051	2,100	63
	Field crop, high-acreage	0.1 lb ai/acre	200 acres	8.4	1.7	0.0021	78,000	0.00043	2,500	75
Mixing/Loading Liquids for Aerial Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	220	0.219	0.19	850	0.00019	5,500	8.1
	Sod	0.21 lb ai/acre	350 acres	220	0.219	0.203	810	0.000201	5,200	7.7
	Field crop, typical	0.3 lb ai/acre	350 acres	220	0.219	0.29	570	0.00029	3,600	5.4
	Field crop, high-acreage	0.2 lb ai/acre	1200 acres	220	0.219	0.66	250	0.00066	1,600	2.4
	Field crop, high-acreage (ULV; Cotton only)	0.1 lb ai/acre	7500 acres	220	0.219	2.06	79	0.0021	510	0.75
				37.6 (gloves)		0.35	460			
Christmas Tree farm	0.1 lb ai/acre	1200 acres	220	0.219	0.33	500	0.00033	3,200	4.8	
Mixing/Loading Liquids for Airblast Application	Nursery (ornamentals, vegetables, trees, container stock)	0.125 lb ai/acre	20 acres	220	0.219	0.0069	24,000	0.0000069	150,000	230
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	220	0.219	0.022	7,400	0.0000219	48,000	71
	Christmas Tree farm	0.1 lb ai/acre	40 acres	220	0.219	0.011	15,000	0.000011	95,000	140
Mixing/Loading Liquids for Chemigation Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	220	0.219	0.193	850	0.000191	5,500	8.1
	Sod	0.21 lb ai/acre	350 acres	220	0.219	0.203	810	0.000201	5,200	7.7
	Field crop, typical	0.3 lb ai/acre	350 acres	220	0.219	0.29	570	0.00029	3,600	5.4
	Field crop, high-acreage	0.2 lb ai/acre	350 acres	220	0.219	0.193	850	0.00019	5,500	8.1
Mixing/Loading Liquids for	Nursery (ornamentals, vegetables, trees, container stock)	0.125 lb ai/acre	60 acres	220	0.219	0.021	7,900	0.000021	51,000	75

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	7,900	0.000021	51,000	75
	Sod	0.21 lb ai/acre	80 acres	220	0.219	0.046	3,500	0.000046	23,000	33
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	220	0.219	0.022	7,400	0.000022	48,000	71
	Orchard/Vineyard (Citrus)	0.5 lb ai/acre	40 acres	220	0.219	0.056	2,900	0.000056	19,000	28
	Field crop, typical	0.3 lb ai/acre	80 acres	220	0.219	0.066	2,500	0.000066	16,000	24
	Field crop, high-acreage	0.2 lb ai/acre	200 acres	220	0.219	0.11	1,500	0.00011	9,500	14
Mixing/Loading WSP for Aerial Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	15,000	0.0023	460	14
	Field crop, typical	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	15,000	0.0023	460	14
	Field crop, high-acreage	0.1 lb ai/acre	1200 acres	12.5 (EC)	2.6 (EC)	0.019	8,700	0.0039	270	8.2
Mixing/Loading WSP for Chemigation Application	Orchard/Vineyard	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	15,000	0.0023	460	14
	Field crop, typical	0.2 lb ai/acre	350 acres	12.5 (EC)	2.6 (EC)	0.011	15,000	0.0023	460	14
Mixing/Loading WSP for Groundboom Application	Orchard/Vineyard	0.2 lb ai/acre	40 acres	12.5 (EC)	2.6 (EC)	0.0013	130,000	0.00026	4,000	120
	Orchard/Vineyard (Citrus)	0.5 lb ai/acre	40 acres	12.5 (EC)	2.6 (EC)	0.0031	52,000	0.00090	1,200	37
	Field crop, typical	0.2 lb ai/acre	80 acres	12.5 (EC)	2.6 (EC)	0.0025	65,000	0.00052	2,000	60
	Field crop, high-acreage	0.1 lb ai/acre	200 acres	12.5 (EC)	2.6 (EC)	0.0031	52,000	0.00065	1,600	48
Applicator										
Applying Sprays with Aerial Application Equipment	Orchard/Vineyard	0.2 lb ai/acre	350 acres	2.08 (EC)	0.0049 (EC)	0.0018	89,000	0.0000043	240,000	800
	Sod	0.21 lb ai/acre	350 acres	2.08 (EC)	0.0049 (EC)	0.0019	86,000	0.0000045	230,000	770
	Field crop, typical	0.3 lb ai/acre	350 acres	2.08 (EC)	0.0049 (EC)	0.0027	60,000	0.0000064	160,000	540
	Field crop, high-acreage	0.2 lb ai/acre	1200 acres	2.08 (EC)	0.0049 (EC)	0.0062	26,000	0.000015	71,000	230
	Field crop, high-acreage (ULV – Cotton only)	0.1 lb ai/acre	7500 acres	2.08 (EC)	0.0049 (EC)	0.020	8,400	0.000046	23,000	76
	Christmas Tree farm	0.1 lb ai/acre	1200 acres	2.08 (EC)	0.0049 (EC)	0.0031	52,000	0.0000074	140,000	470

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin.										
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 ARI ⁶
				Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
Applying Sprays with Airblast Application Equipment	Nursery (ornamentals, vegetables, trees, container stock)	0.125 lb ai/acre	20 acres	1770	4.71	0.0554	3,000	0.00015	7,100	27
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	1770	4.71	0.18	920	0.00047	2,200	8.2
	Christmas Tree farm	0.1 lb ai/acre	40 acres	1770	4.71	0.089	1,800	0.00024	4,500	16
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	22,000	0.000032	33,000	180
	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.125 lb ai/acre	60 acres	78.6	0.34	0.0074	22,000	0.000032	33,000	180
	Sod	0.21 lb ai/acre	80 acres	78.6	0.34	0.017	9,900	0.000071	15,000	83
	Orchard/Vineyard	0.2 lb ai/acre	40 acres	78.6	0.34	0.0079	21,000	0.000034	31,000	170
	Orchard/Vineyard (Citrus)	0.2 lb ai/acre	40 acres	78.6	0.34	0.020	8,400	0.000085	12,000	69
	Field crop, typical	0.3 lb ai/acre	80 acres	78.6	0.34	0.024	6,900	0.000102	10,000	57
	Field crop, high-acreage	0.2 lb ai/acre	200 acres	78.6	0.34	0.039	4,200	0.00017	6,200	35
Applying Granules with Aerial Application Equipment	Field crop, typical	0.1 lb ai/acre	350 acres	1.7 (EC)	1.3 (EC)	0.000744	220,000	0.00057	1,800	58
	Field crop, high-acreage	0.1 lb ai/acre	1200 acres	1.7 (EC)	1.3 (EC)	0.0026	64,000	0.0015	540	18
Applying Granules with a Tractor-Drawn Spreader	Sod	0.4 lb ai/acre	80 acres	9.9	1.2	0.0040	41,000	0.00048	2,200	62
	Field crop, typical	0.3 lb ai/acre	80 acres	9.9	1.2	0.0030	55,000	0.00036	2,900	82
	Field crop, high-acreage	0.1 lb ai/acre	200 acres	9.9	1.2	0.0030	55,000	0.00030	3,500	96
Flagger										
Flagging for Aerial Applications (Sprays)	Orchard/Vineyard	0.2 lb ai/acre	350 acres	11	0.35	0.0096	17,000	0.00031	3,400	68
	Sod	0.21 lb ai/acre	350 acres	11	0.35	0.0101	16,000	0.00032	3,300	65
	Field crop, typical	0.3 lb ai/acre	350 acres	11	0.35	0.015	11,000	0.00046	2,300	45
	Field crop, high-acreage	0.2 lb ai/acre	350 acres	11	0.35	0.0096	17,000	0.00031	3,400	68
	Field crop, typical	0.1 lb ai/acre	350 acres	2.75	0.15	0.0012	140,000	0.000066	16,000	390

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin.										
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	140,000	0.000066	16,000	390
Mixer/Loader/Applicator										
Mixing/Loading/ Applying Liquids with a Backpack	Orchard/Vineyard	0.0125 lb ai/gallon	40 gallons	8260	2.58	0.052	3,200	0.000016	65,000	32
	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.00125 lb ai/gallon	40 gallons	13200	140	0.0083	20,000	0.000088	12,000	130
	Christmas Tree farm	0.005 lb ai/gallon	40 gallons	58400	69.1	0.15	1,100	0.00017	6,100	10
	Nursery (ornamentals, vegetables, trees, container stock)	0.00125 lb ai/gallon	40 gallons	58400	69.1	0.037	4,500	0.000043	24,000	43
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	2,600	0.000019	56,000	26
	Christmas Tree farm	0.005 lb ai/gallon	40 gallons	100000	30	0.25	650	0.000075	14,000	6.4
	Nursery (ornamentals, vegetables, trees, container stock)	0.00125 lb ai/gallon	40 gallons	100000	30	0.063	2,600	0.000019	56,000	26
	Mounds/nests	0.00078 lb ai/gallon	40 gallons	100000	30	0.039	4,200	0.000012	90,000	41
Mixing/Loading/ Applying Liquids with a Mechanically-pressurized Handgun	Orchard/Vineyard	0.0125 lb ai/gallon	1000 gallons	6050	8.68	0.95	170	0.0014	770	1.6
	Greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	0.00125 lb ai/gallon	1000 gallons	3500	120	0.055	3,000	0.0019	560	12
	Christmas Tree farm	0.005 lb ai/gallon	1000 gallons	6050	8.68	0.38	430	0.00054	1,900	4.0
	Nursery (ornamentals, vegetables, trees, container stock)	0.00125 lb ai/gallon	1000 gallons	6050	8.68	0.095	1,700	0.00014	7,700	16
	Field crop, typical	0.01 lb ai/gallon	1000 gallons	6050	8.68	0.76	220	0.0011	960	2.1
				6050	8.68	2.3	72	0.0033	320	0.67

Table D.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Agricultural Uses of Bifenthrin.										
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	210			1.8
		0.04 lb ai/gallon (Tobacco – Soil At-plant)		6050	8.68	3.03	54	0.0043	240	0.51
				2050 (gloves)		1.03	160			1.3
	Trees grown for non-commercial purposes (private lands, parks, or rangeland)	0.6 lb ai/A	5 acres	6050	8.68	0.23	720	0.00033	3,200	6.7
Mixing/Loading/ Applying WSP Formulations with a Backpack	Orchard/Vineyard	0.0125 lb ai/gallon	40 gallons	8260	2.58	0.052	3,200	0.000016	65,000	32
Mixing/Loading/ Applying WSP Formulations with a Mechanically-pressurized Handgun	Orchard/Vineyard	0.0125 lb ai/gallon	1000 gallons	6050	8.68	0.95	170	0.0014	770	1.6
	Field crop, typical	0.01 lb ai/gallon	1000 gallons	6050	8.68	0.76	220	0.0011	960	2.1
Loading/ Applying Granule Formulations with a Rotary Spreader	Sod	0.4 lb ai/acre	5 acres	440	10	0.011	15,000	0.00025	4,200	72
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	6,100	0.00040	2,600	36
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	23 (gloves)	0.34	0.027	6,100	0.00040	2,600	36
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	23 (gloves)	0.34	0.073	2,200	0.0011	970	13
	Dried Peas and Beans	0.00075 lb ai/lb seed	281,250 lb seed	23 (gloves)	0.34	0.061	2,700	0.00090	1,200	16
	Soybean	0.00075 lb ai/lb seed	281,250 lb seed	23 (gloves)	0.34	0.061	2,700	0.00090	1,200	16
	Succulent Peas and Beans	0.00075 lb ai/lb seed	339,500 lb seed	23 (gloves)	0.34	0.073	2,200	0.0011	970	13
	Head and Stem Brassica	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	250,000	0.0000096	110,000	1,500

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 ARI ⁶
				Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	250,000	0.0000096	110,000	1,500
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	250,000	0.0000096	110,000	1,500
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	3,000 lb seed	23 (gloves)	0.34	0.00065	250,000	0.0000096	110,000	1,500
	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	250,000	0.0000096	110,000	1,500
Sewer for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	125,000 lb seed	0.0062	0.23	0.0000073	23,000,000	0.00027	3,900	130
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	0.0062	0.23	0.0000073	23,000,000	0.00027	3,900	130
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	0.0062	0.23	0.000020	8,300,000	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	10,000,000	0.00061	1,700	57
	Soybean	0.00075 lb ai/lb seed	281,250 lb seed	0.0062	0.23	0.000016	10,000,000	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	8,300,000	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	940,000,000	0.0000065	160,000	5,300
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	0.0062	0.23	0.00000018	940,000,000	0.0000065	160,000	5,300
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	0.0062	0.23	0.00000018	940,000,000	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	940,000,000	0.0000065	160,000	5,300
Bagger for Flowable Seed	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	940,000,000	0.0000065	160,000	5,300
	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	125,000 lb seed	9.1	0.16	0.011	15,000	0.00019	5,600	83
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	9.1	0.16	0.011	15,000	0.00019	5,600	83
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	9.1	0.16	0.029	5,600	0.00051	2,100	31
	Dried Peas and Beans	0.00075 lb ai/lb seed	281,250 lb seed	9.1	0.16	0.024	6,800	0.00042	2,500	37

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	281,250 lb seed	9.1	0.16	0.024	6,800	0.00042	2,500	37
	Succulent Peas and Beans	0.00075 lb ai/lb seed	339,500 lb seed	9.1	0.16	0.029	5,600	0.00051	2,100	31
	Head and Stem Brassica	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	640,000	0.0000045	230,000	3,500
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	640,000	0.0000045	230,000	3,500
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	640,000	0.0000045	230,000	3,500
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	3,000 lb seed	9.1	0.16	0.00026	640,000	0.0000045	230,000	3,500
	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	640,000	0.0000045	230,000	3,500
Multiple Activities for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	125,000 lb seed	42 (gloves)	1.6	0.049	3,300	0.0019	560	12
	Cotton	0.00075 lb ai/lb seed	125,000 lb seed	42 (gloves)	1.6	0.049	3,300	0.0019	560	12
	Corn	0.00075 lb ai/lb seed	339,500 lb seed	42 (gloves)	1.6	0.13	1,200	0.0051	210	4.4
	Dried Peas and Beans	0.00075 lb ai/lb seed	281,250 lb seed	42 (gloves)	1.6	0.11	1,500	0.0042	250	5.4
	Soybean	0.00075 lb ai/lb seed	281,250 lb seed	42 (gloves)	1.6	0.11	1,500	0.0042	250	5.4
	Succulent Peas and Beans	0.00075 lb ai/lb seed	339,500 lb seed	42 (gloves)	1.6	0.13	1,200	0.0051	210	4.4
	Head and Stem Brassica	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	140,000	0.000045	23,000	500
	Cucurbits	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	140,000	0.000045	23,000	500
	Lettuce, head	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	140,000	0.000045	23,000	500
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	140,000	0.000045	23,000	500
	Fruiting Vegetables (eggplant, bell and non-bell pepper, groundcherry, pepino, tomato, tomatillo)	0.00075 lb ai/lb seed	3,000 lb seed	42 (gloves)	1.6	0.0012	140,000	0.000045	23,000	500
Planters for Flowable Seed	Canola, Crambe, Rapeseed	0.00075 lb ai/lb seed	524.26 lb seed	250 (gloves)	3.4	0.0012	130,000	0.000017	63,000	800

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 ARI ⁶
				Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
	Cotton	0.00075 lb ai/lb seed	3,778 lb seed	250 (gloves)	3.4	0.0089	18,000	0.00012	8,800	110
	Corn (field)	0.00075 lb ai/lb seed	5,915 lb seed	250 (gloves)	3.4	0.014	12,000	0.00019	5,600	73
	Corn (pop)	0.00075 lb ai/lb seed	4,409 lb seed	250 (gloves)	3.4	0.010	16,000	0.00014	7,500	98
	Corn (sweet)	0.00075 lb ai/lb seed	6,638 lb seed	250 (gloves)	3.4	0.016	11,000	0.00021	5,000	66
	Dried Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed	250 (gloves)	3.4	0.061	2,700	0.00083	1,300	17
	Soybean	0.00075 lb ai/lb seed	33,333 lb seed	250 (gloves)	3.4	0.078	2,100	0.0011	990	13
	Succulent Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed	250 (gloves)	3.4	0.061	2,700	0.00083	1,300	17
	Head and Stem Brassica	0.00075 lb ai/lb seed	211 lb seed	250 (gloves)	3.4	0.00049	330,000	0.0000067	160,000	2,000
	Cucurbits	0.00075 lb ai/lb seed	929 lb seed	250 (gloves)	3.4	0.0022	75,000	0.000030	35,000	460
	Lettuce, head	0.00075 lb ai/lb seed	78.41 lb seed	250 (gloves)	3.4	0.00018	890,000	0.0000025	420,000	5,400
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	63 lb seed	250 (gloves)	3.4	0.00015	1,100,000	0.0000020	530,000	6,800
	Fruiting Vegetables - Tomato	0.00075 lb ai/lb seed	87 lb seed	250 (gloves)	3.4	0.000204	800,000	0.0000028	380,000	4,900
	Fruiting Vegetables - Eggplant	0.00075 lb ai/lb seed	605 lb seed	250 (gloves)	3.4	0.0014	120,000	0.000019	54,000	720
	Fruiting Vegetables -Bell pepper	0.00075 lb ai/lb seed	112 lb seed	250 (gloves)	3.4	0.00026	630,000	0.0000036	300,000	3,900
Fruiting Vegetables -Non Bell pepper	0.00075 lb ai/lb seed	334 lb seed	250 (gloves)	3.4	0.00078	210,000	0.000011	98,000	1,300	
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	150,000	0.0000011	970,000	1,400
	Cotton	0.00075 lb ai/lb seed	3,778 lb seed			0.0078	21,000	0.0000078	140,000	200
	Corn (field)	0.00075 lb ai/lb seed	5,915 lb seed			0.012	13,000	0.000012	86,000	120
	Corn (pop)	0.00075 lb ai/lb seed	4,409 lb seed			0.0091	18,000	0.0000091	120,000	170
	Corn (sweet)	0.00075 lb ai/lb seed	6,638 lb seed			0.014	12,000	0.000014	77,000	110
	Dried Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed			0.054	3,000	0.000054	20,000	29
	Soybean	0.00075 lb ai/lb seed	33,333 lb seed			0.069	2,400	0.000069	15,000	23
	Succulent Peas and Beans	0.00075 lb ai/lb seed	26,136 lb seed			0.054	3,000	0.000054	20,000	29

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 ARI ⁶
				Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
	Head and Stem Brassica	0.00075 lb ai/lb seed	211 lb seed			0.00044	380,000	0.00000043	2,400,000	3,600
	Cucurbits	0.00075 lb ai/lb seed	929 lb seed			0.0019	86,000	0.0000019	550,000	820
	Lettuce, head	0.00075 lb ai/lb seed	78.41 lb seed			0.00016	1,000,000	0.00000016	6,500,000	9,600
	Leafy Brassicas, Turnip Greens	0.00075 lb ai/lb seed	63 lb seed			0.00013	1,300,000	0.00000013	8,100,000	12,000
	Fruiting Vegetables - Tomato	0.00075 lb ai/lb seed	87 lb seed			0.00018	910,000	0.00000018	5,900,000	8,700
	Fruiting Vegetables - Eggplant	0.00075 lb ai/lb seed	605 lb seed			0.0013	130,000	0.0000012	850,000	1,200
	Fruiting Vegetables -Bell pepper	0.00075 lb ai/lb seed	112 lb seed			0.00023	710,000	0.00000023	4,600,000	6,800
	Fruiting Vegetables -Non Bell pepper	0.00075 lb ai/lb seed	334 lb seed			0.00069	240,000	0.00000069	1,500,000	2,300

1 Assessment based on maximum registered 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 PPE: 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 (ug/lb ai) × Conversion Factor (0.001 mg/ug) × 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 = 163.71 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.											
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 ARI ⁶
					Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
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	97,000	0.00034	3,100	93
		Golf course (tees and greens only)	0.4 lb ai/acre	5 acres	8.4	1.7	0.00021	780,000	0.000043	25,000	750
Mixing/Loading Liquids for Impregnation	On-farm treatment	Fertilizer, dry bulk, impregnated	0.23 lb ai/acre	160 acres	220	0.219	0.101	1,600	0.000101	10,000	15
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	2,300,000	0.000000071	15,000,000	22,000
Mixing/Loading Liquids for Groundboom	Broadcast	Golf course (tees and greens only)	0.2 lb ai/acre	5 acres	220	0.219	0.0028	60,000	0.0000027	380,000	570
		Golf course (fairways, tees, greens)	0.2 lb ai/acre	40 acres	220	0.219	0.022	7,400	0.000022	48,000	71
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	170,000	0.0000043	250,000	1,400
		Golf course (fairways, tees, greens)	0.2 lb ai/acre	40 acres	78.6	0.34	0.0079	21,000	0.000034	31,000	170

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 ARI ⁶
					Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
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	36,000	0.00055	1,900	54
		Field crop, high-acreage	0.23 lb ai/acre	160 acres	9.9	1.2	0.0046	36,000	0.00055	1,900	54
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	83,000	0.00024	4,400	120
		Golf course (tees and greens only)	0.4 lb ai/acre	5 acres	9.9	1.2	0.00025	660,000	0.000030	35,000	990
Applying RTU (PL) Aerosol can	Crack and Crevice	Warehouse	0.00075 lb ai/can	10 cans	190000	1300	0.018	1,300	0.00012	8,600	69
		Residential Living Spaces (homes, apartments)	0.00075 lb ai/can	10 cans	190000	1300	0.018	1,300	0.00012	8,600	69
		Childcare center/schools/institutions	0.00075 lb ai/can	10 cans	190000	1300	0.018	1,300	0.00012	8,600	69
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	1,100	0.00018	5,800	10
		Landscaping, plants/flowers	0.0052 lb ai/gallon	40 gallons	58400	69.1	0.15	1,100	0.00018	5,800	10
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.0052 lb ai/gallon	40 gallons	58400	69.1	0.15	1,100	0.00018	5,800	10
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	7,600	0.0000067	160,000	75
	Broadcast	Foundations/perimeter	0.0052 lb ai/gallon	40 gallons	8260	2.58	0.022	7,600	0.0000067	160,000	75
		Structural (termiteicide)	0.0104 lb ai/gallon	40 gallons	2510	30	0.013	13,000	0.00016	6,700	82

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 ARI ⁶
					Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0106 lb ai/gallon	40 gallons	2510	30	0.013	12,000	0.00016	6,600	78
		Poultry/livestock house/horse barn/feed lot	0.0052 lb ai/gallon	40 gallons	2510	30	0.0065	25,000	0.000078	13,000	160
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	630	0.000078	13,000	6.2
		Landscaping, plants/flowers	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
		Poultry/livestock house/horse barn/feed lot	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
		Foundations/perimeter	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
		Interior landscaping	0.23 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0106 lb ai/gallon	40 gallons	100000	30	0.53	310	0.00016	6,600	3.1
	Spot	Mounds/nests	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
	Broadcast	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
	Crack and Crevice	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
		Warehouse	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9

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 ARI ⁶
					Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
		Residential Living Spaces (homes, apartments)	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
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	11,000	0.000024	44,000	100
		Golf course (fairways, tees, greens)	0.2 lb ai/acre	5 acres	1140	1.9	0.014	11,000	0.000024	44,000	100
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.23 lb ai/acre	5 acres	1140	1.9	0.016	10,000	0.000027	38,000	93
		Landscaping, trees/shrubs/bushes	0.0052 lb ai/gallon	1000 gallons	6050	8.68	0.39	420	0.00056	1,900	3.9
		Structural (termiticide)	0.0104 lb ai/gallon	1000 gallons	1800	79	0.23	700	0.0103	100	2.3
		Warehouse	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	1,400	0.0051	200	4.5
		Poultry/livestock house/horse barn/feed lot	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	1,400	0.0051	200	4.5
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0106 lb ai/gallon	1000 gallons	1800	79	0.24	680	0.011	100	2.2
Mixing/Loading/ Applying Liquid Formulations with Injector	Broadcast	Structural (termiticide)	0.0104 lb ai/gallon	1000 gallons	1300	2.2	0.17	970	0.00029	3,700	9.0
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	25,000	0.000078	13,000	160
		Structural (termiticide)	0.0052 lb ai/gallon	40 gallons	2510	30	0.0065	25,000	0.000078	13,000	160

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 ARI ⁶
					Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
		Foundations/perimeter	0.0052 lb ai/gallon	40 gallons	8260	2.58	0.022	7,600	0.0000067	160,000	75
Mixing/Loading/ Applying WSP Formulations with Manually-pressurized Handwand	Broadcast	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
	Crack and Crevice	Food handling establishment	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
		Warehouse	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
		Residential Living Spaces (homes, apartments)	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
		Childcare center/schools/institutions	0.0052 lb ai/gallon	40 gallons	29000	1100	0.075	2,200	0.0029	370	7.9
	Broadcast	Foundations/perimeter	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2
Spot	Mounds/nests	0.0052 lb ai/gallon	40 gallons	100000	30	0.26	630	0.000078	13,000	6.2	
Mixing/Loading/ Applying WSP Formulations with Mechanically-pressurized Handgun	Broadcast	Structural (termiticide)	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	1,400	0.0051	200	4.5
		Warehouse	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	1,400	0.0051	200	4.5
		Structural (e.g., bridges, shipyards, home decks, foundations)	0.0052 lb ai/gallon	1000 gallons	1800	79	0.12	1,400	0.0051	200	4.5
Loading/Applying Granule Formulations with a Belly grinder	Broadcast	Landscaping, trees/shrubs/bushes	0.5 lb ai/acre	1 acres	10000	62	0.0625	2,600	0.000388	2,700	20
		Landscaping, plants/flowers	0.5 lb ai/acre	1 acres	10000	62	0.0625	2,600	0.000388	2,700	20

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 ARI ⁶
					Dermal	Inhalation	Dose ⁴ (mg/kg-day)	MOE ⁵	Dose ⁴ (mg/kg-day)	MOE ⁵	
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.5 lb ai/acre	1 acres	10000	62	0.0625	2,600	0.000388	2,700	20
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	15,000	0.00025	4,200	72
		Golf course (fairways, tees, greens)	0.4 lb ai/acre	5 acres	440	10	0.011	15,000	0.00025	4,200	72
		Landscaping, turf (lawns, athletic fields, parks, etc.)	0.5 lb ai/acre	5 acres	440	10	0.0138	12,000	0.000313	3,400	58
Loading/Applying Liquid Formulations with Brush/roller	Broadcast	Wood treatment	0.00428 lb ai/gallon	5 gallons	180000	280	0.048	3,400	0.000075	14,000	32

1 Assessment based on maximum registered 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 (ug/lb ai) × Conversion Factor (0.001 mg/ug) × 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 = 163.71 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/TTR 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	3,200
	Cranberry	0.1	1100	Hand harvesting (raking), scouting	0	0.27	0.030	5,500
	Strawberry	0.2	1100	Hand harvesting	0	0.54	0.059	2,800
Bunch/bundle	Hop	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Tobacco	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Field / row crop, low / medium	Alfalfa	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Canola, Crambe, Rapeseed	0.04	1100	Scouting	0	0.11	0.012	14,000
	Cotton	0.1	5050	Harvesting, Mechanical, Trampler	0	0.20	0.101	1,600
	Grass (forage, fodder and hay, grass grown for seed), Pasture and Rangeland	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Meadowfoam (grown for seed)	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Peanut	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Soybean	0.1	1100	Scouting	0	0.27	0.030	5,500
	Succulent Peas and Beans, Dried Peas and Beans	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Field / row crop, tall	Corn, field	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Corn, pop	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Corn, sweet, grain	0.1	8800	Detasseling, Hand; Harvesting, Hand	0	0.27	0.236	690
	Corn, sweet, processing	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Tree, "fruit", deciduous	Nectarine	0.2	3600	Thinning Fruit	0	0.54	0.193	850
	Peach	0.2	3600	Thinning Fruit	0	0.54	0.193	850
	Pome Fruit (Pear, Apple)	0.2	3600	Thinning Fruit	0	0.54	0.193	850
	Pomegranate	0.2	1400	Harvesting, Hand	0	0.54	0.075	2,200

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/TTR 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	5,800
	Christmas tree	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Tree, "nut"	Tree Nut - Almond	0.2	580	Scouting	0	0.54	0.031	5,300
	Tree Nut - Hazelnut	0.2	580	Scouting	0	0.54	0.031	5,300
	Tree Nut - Macadamia nut	0.2	580	Pruning, Hand; Scouting	0	0.54	0.031	5,300
	Tree Nut - Pecan	0.2	580	Pruning, Hand; Scouting	0	0.54	0.031	5,300
	Tree Nut - Pistachio	0.2	1400	Harvesting, Hand (net)	0	0.54	0.075	2,200
	Tree Nut - Walnut, English	0.2	580	Scouting	0	0.54	0.031	5,300
Turf / sod	Golf Course	0.4 (granular)	3700	Maintenance	0	0.0014	0.00052	320,000
		0.21 (liquid)				0.061	0.022	7,300
	Sod	0.4 (granular)	6700	Maintenance; Harvesting, Slab; Transplanting/Planting	0	0.0014	0.00094	170,000
		0.21 (liquid)				0.064	0.043	3,800
Unassigned	Nursery Crop (Ornamentals, Non-bearing Plants)	0.125	1900	Irrigation (hand set)	0	0.34	0.064	2,600
	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	20,000
Vegetable, "root"	Tuberous and Corm Vegetables - Carrot	0.3	1900	Irrigation (hand set)	0	0.80	0.153	1,100
	Tuberous and Corm	0.3	1900	Irrigation (hand set)	0	0.80	0.153	1,100

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/TTR Residue ³ (ug/cm ²)	Dose ⁴ (mg/kg-day)	MOE ⁵
	Vegetables - Potato							
Vegetable, cucurbit	Cucurbits - Cantaloupe, Cucumber, Gourd, Pumpkin, Summer Squash, Winter Squash, Watermelon	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Vegetable, Fruiting	Fruiting Vegetables - Eggplant, Bell Pepper, Chili Pepper, Tomato, Tomato Processing	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Okra	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Vegetable, head and stem Brassica	Head and Stem Brassica - Broccoli	0.1	4200	Scouting; Harvesting, Hand; Weeding, Hand	0	0.27	0.113	1,500
	Head and Stem Brassica - Brussels Sprouts	0.1	4200	Scouting; Harvesting, Hand; Weeding, Hand; Topping	0	0.27	0.113	1,500
	Head and Stem Brassica - Cabbage	0.1	4200	Weeding, Hand	0	0.27	0.113	1,500
	Head and Stem Brassica - Cauliflower	0.1	4200	Scouting; Harvesting, Hand; Tying/Training; Weeding, Hand	0	0.27	0.113	1,500
Vegetable, leafy	Cilantro, Coriander	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Head and Stem Brassica - Cabbage, chinese, Napa	0.1	4200	Weeding, Hand	0	0.27	0.113	1,500
	Leafy Brassicas - Cabbage, chinese, Bok choy	0.1	4200	Weeding, Hand	0	0.27	0.113	1,500
	Leafy Brassicas, Turnip Greens - Collards, Kale, Mustard Green, Watercress	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200

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/TTR Residue ³ (ug/cm ²)	Dose ⁴ (mg/kg-day)	MOE ⁵
	Leafy Petiole Vegetables - Celery	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Spinach	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Vegetable, leafy, except Brassica	Greens, Leafy	0.1	1100	Hand Harvesting	0	0.27	0.030	5,500
	Parsley	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Spinach	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Vegetable, stem / stalk	Artichoke	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
Vine / trellis	Bushberry	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Caneberry	0.1	1900	Irrigation (hand set)	0	0.27	0.051	3,200
	Grape, wine	0.1	10100	Tying/Training; Harvesting, Hand; Leaf Pulling	0	0.27	0.271	600
	Grape, juice	0.1	10100	Tying/Training; Harvesting, Hand; Leaf Pulling	0	0.27	0.271	600
	Grape, table	0.1	19300	Girdling, Turning	0	0.27	0.518	320
	Grape, raisin	0.1	5500	Tying/Training; Harvesting, Hand; Leaf Pulling	0	0.280	0.148	1,100

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/cm²; Study application rate = 0.002 lb ai/gallon

Liquid Sod/Turf: MRID 44955201 (turf): Day 0 concentration = 0.0624 ug/cm²; Study application rate = 0.2 lb ai/A

Granular Sod/Turf: MRID 50544404 (turf): 0DAT 3 = 0.0014 ug/cm²; Study application rate = 0.2 lb ai/A

Other crops: MRID 44684401 (strawberries): Day 0 concentration = 0.537 ug/cm²; Study application rate = 0.2 lb ai/A

4 Daily Dermal Dose = [DFR (ug/cm²) × Transfer Coefficient × 0.001 mg/ug × 8 hrs/day] ÷ BW (80 kg).

5 MOE = POD (163.7 mg/kg/day) / Daily Dermal Dose.

Appendix E. International Residue Limit Status Sheet

(Bifenthrin, PC 128852; 02/2020)

E.1. Bifenthrin Summary of US and International Tolerances and Maximum Residue Limits: 40 CFR §180.442(a)					
<i>Residue Definition:</i>					
US	Canada			Mexico	Codex
40 CFR §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 ¹	<i>Tolerance (ppm)/Maximum Residue Limit (mg/kg)</i>				
	US Established	HED-Recommended	Canada	Mexico ²	Codex
Almond hulls	2.0	2			
Artichoke, globe	1.0	1			
Banana ¹	0.1	0.1			0.1
Beet, garden, leaves	15	15			
Beet, garden, roots	0.45	0.5	0.5		
Brassica, leafy greens, subgroup 4-16B	3.5	4	4 kales		4 mustard greens
Broccoli, chinese	-	4	4		0.4 (brassica, cole or cabbage)
Bushberry subgroup 13-07B	1.8	3	3 highbush blueberries		3 blueberries
Cabbage	4.0	7	7 cabbages		0.4 (brassica, cole or cabbage)
Caneberry subgroup 13-07A	1.0	1	1 raspberry		1 blackberry and dewberries (including boysenberry and loganberry) and raspberries (red and black)
Cattle, fat	1.0	1	0.1		
Cattle, meat byproducts	0.10	0.2	0.05		0.2
Cattle, meat	0.5	3	0.05		3
Celtuce	-	3			
Cilantro, dried leaves	25	25			
Cilantro, fresh leaves	6.0	6			
Coriander, seed	5.0	5			
Corn, field, forage	3.0	3			
Corn, field, grain	0.05	0.05			0.05 (*)
Corn, field, stover	5.0	15			15 maize fodder (dry)
Corn, pop, grain	0.05	0.05			
Corn, pop, stover	5.0	5			
Corn, sweet, forage	3.0	3			
Corn, sweet, kernel plus cob with husk removed	0.05	0.05			
Corn, sweet, stover	5.0	5			
Cotton, undelinted seed	0.5	0.5			0.5

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40 CFR §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 ¹	<i>Tolerance (ppm)/Maximum Residue Limit (mg/kg)</i>				
	US Established	HED-Recommended	Canada	Mexico ²	Codex
Eggplant	0.05	0.3	0.5		0.3
Egg	0.05	0.05	0.01		
Fennel, florence, fresh leaves and stalk	-	3			
Fruit, citrus, group 10-10	0.05	0.05			0.05
Goat, fat	1.0	1	0.1		
Goat, meat byproducts	0.10	0.2	0.05		0.2
Goat, meat	0.5	3	0.05		3
Grain, aspirated fractions	70	70			
Grape	0.2	0.3			0.3
Groundcherry	0.5	0.5	0.5		
Herb subgroup 19A	0.05	0.05			
Hog, fat	1.0	1	0.1		
Hog, meat byproducts	0.10	0.2	0.05		0.2
Hog, meat	0.5	3	0.05		3
Hop, dried cones	10.0	20			20
Horse, fat	1.0	1	0.1		
Horse, meat byproducts	0.10	0.2	0.05		0.2
Horse, meat	0.5	3	0.05		3
Kohlrabi	-	3			
Leafy petiole vegetable subgroup 22B	-	3	3 celery		
Lettuce, head	3.0	4	4		
Mayhaw	1.4	1.5	1.5		
Milk	0.1	0.2			0.2
Milk, fat	1.0	3	0.02		3
Nut, tree, group 14-12	0.05	0.05			0.05
Okra	0.50	0.5	0.5		0.2
Pea and bean, dry shelled, except soybean, subgroup 6C	0.15	0.15	0.15		0.3
Pea and bean, succulent shelled, subgroup 6B	0.05	0.05	0.05		0.05
Peanut	0.05	0.05			
Pear	0.5	0.9	0.9		
Pepino	0.5	0.5	0.5		
Pepper, bell	0.5	0.5	0.5		0.5
Pepper, nonbell	0.5	0.5	0.5		0.5 5 dried chili pepper
Poultry, fat	0.05	0.05	0.05		
Poultry, meat byproducts	0.05	0.05	0.05		
Poultry, meat	0.05	0.05	0.02		
Radish, tops	4.5	4.5			4
Rapeseed, seed	0.05	0.05			0.05 0.1 rapeseed oil, edible

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<i>Residue Definition:</i>					
US	Canada			Mexico	Codex
40 CFR §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 ¹	<i>Tolerance (ppm)/Maximum Residue Limit (mg/kg)</i>				
	US Established	HED-Recommended	Canada	Mexico ²	Codex
Sheep, fat	1.0	1	0.1		
Sheep, meat byproducts	0.1	0.2	0.05		0.2
Sheep, meat	0.5	3	0.05		3
Soybean, hulls	0.50	0.5			
Soybean, refined oil	0.30	0.3			
Soybean, seed	0.2	0.2	0.2		0.3 pulses
Spinach	0.2	0.3	0.3		
Strawberry	3.0	3			1
Swiss chard	-	3	3		
Tea, dried ¹	30	30	30		30
Tomato	0.15	0.3	0.5		0.3
Vegetable, brassica, head and stem, group 5-16	0.6	0.9	0.9 broccoli and cauliflower		0.4 (brassica, cole or cabbage)
Vegetable, cucurbit, group 9	0.4	0.5	0.5 squashes and cucumber		
Vegetable, legume, edible podded, subgroup 6A	0.6	0.8	0.8 edible podded pea		
Vegetable, root, subgroup 1B, except sugar beet and garden beet	0.10	0.1	0.05 carrot and garden beet		0.05 root and tuber vegetables
Vegetable, tuberous and corm, subgroup 1C	0.05	0.05	0.05 potatoes		0.05

Completed using Global MRL. 12-Feb-2020

¹ Includes all commodities relevant to this chemical.

² Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

E.2. Bifenthrin Summary of US and International Tolerances and Maximum Residue Limits: 40 CFR §180.442(b)					
<i>Residue Definition:</i>					
US	Canada			Mexico	Codex
40 CFR §180.442(b) <i>Section 18 emergency exemptions.</i> 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 ¹	<i>Tolerance (ppm)/Maximum Residue Limit (mg/kg)</i>				
	US Established	HED-Recommended	Canada	Mexico ²	Codex
Apple	0.5				
Avocado	0.50				
Nectarine	0.5				
Peach	0.5				
Pomegranate	0.50				
Completed using Global MRL. 10-Jan-2020					

¹ Includes all commodities relevant to this chemical.

² Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

E.3 Bifenthrin Summary of US and International Tolerances and Maximum Residue Limits: 40 CFR §180.442(c)					
<i>Residue Definition:</i>					
US	Canada			Mexico	Codex
40 CFR §180.442(c) <i>Tolerances with regional registrations.</i> 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 ¹	<i>Tolerance (ppm)/Maximum Residue Limit (mg/kg)</i>				
	US Established	HED-Recommended	Canada	Mexico ²	Codex
Grass, forage, fodder and hay, group 17, forage	4.0	4			
Grass, forage, fodder and hay, group 17, hay	15	15			
Completed using Global MRL. 10-Jan-2020					

¹ Includes all commodities relevant to this chemical.

² Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

Appendix F. Pesticide Use Pattern

Table. F.1. 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	0.0041 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
			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	0.0000012 lb ai/ft ² or 0.5 lb ai/A	279-3343
	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	0.000012 lb ai/ft ²	279-3343
	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

Use Site	Formulation	Application Type	Application Equipment	Application Timing	Maximum Application Rate	Representative Label
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.

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

Table F.2. 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
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
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

Table F.2. 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
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 Vegetables (i.e. Potato, Sweet potato)	Liquid	Foliar	Broadcast	Air, Ground, Chemigation	0.1 lb ai/A or 0.01 lb ai/gal	279-3313; 279-3302
	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)

Table F.2. 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
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
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 or 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.3. 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 (indoor and outdoor surfaces/voids)	Liquid	Spot, crack and crevice	Sprayers	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24
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 0.2 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	0.4 lb ai/A	279-3343
	Liquid	Broadcast	Ground	When needed	2.3 lb ai/A 0.0052 lb ai/gal 0.23 lb ai/A	279-3169 and 279-3152 279-3206 ⁺
Ornamental Lawns & Turf - Non-residential (institutional, public, commercial or industrial)	Granular	Broadcast, Spot, Perimeter	Ground	When needed	0.4 lb ai/A 0.2 lb ai/A	279-9547 and 279-3343 *
	Liquid	Broadcast	Ground	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24 and 279-3169

Table F.3. 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
buildings; parks, recreational areas or athletic fields)						
Outdoor Ornamental Trees/Shrubs/Flowers	Granular	Soil Broadcast, Spot, Perimeter	Ground	When needed	0.4 lb ai/A	279-9547 and 279-3343
	Liquid, WP/WSP	Foliar, Trunks	Sprayers (tank, backpack, handheld, coarse, low pressure); Paint brush; Soil drench; soil injection	When needed	0.23 lb ai/A or 0.0052 lb ai/gal	70506-24; 432-1415; 8033-96
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	0.5 lb ai/A	279-3343
	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

* Lower rates assessed to represent registered products highlighted in submitted public comments. EPA response to public comments can be found in D44852 (K. Rickard, 02/06/2020).

+ The 2017 DRA (K. Rickard, D434404 and D436605, 08/29/2017) assessed a maximum residential application rate of 2.3 lb ai/A based on EPA Reg. Nos. 279-3169 and 279-3152. Because residential post-application risk estimates of concern from exposure to treated turf have been identified for adults and children 1 to < 2 years old, HED also evaluate a lower application rate of 0.23 lb ai/A for liquid/spray formulations of bifenthrin on residential turf since there may be some discrepancy with the current maximum labeled rate of 2.3 lb ai/A.

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)²¹ 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 (C. Smith, D390098, 09/15/2011) 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 (C. Smith, D390098, 09/15/2011) 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

²¹ Pyrethroid Cumulative Risk Assessment; K. Whitby, D394576, 10/04/2011

0.04, 0.03, and 0.05 for pyrethrins, permethrin, and deltamethrin, respectively. Since the 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.**

- Liquid Turf Transferable Residue (TTR) Data:** A liquid TTR study is available for bifenthrin. A HED review of MRID 44955201 was completed in 2002 (S. Weiss, D284552, 07/31/2002) 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 µg/cm²), 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 µg/cm²), 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 µg/cm²), 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 G.1. The predicted DAT0 residue value of 0.061 µg/cm² from the California site was used to estimate risk on turf.

Location	Formulation	Application Rate (lb ai/acre)	Application Method	R-squared	[C ₀] (µg/cm ²)	[C ₀] (µg/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

Granular Turf Transferable Residue (TTR) Data: A granular TTR study is available for bifenthrin. A HED review of MRID 50544404 was completed in 2018 (K. Rickard, D448449, 10/15/2018). The study was conducted at one site in Fresno, California. Talstar® PL Granular Insecticide, a granular formulation containing 0.2% active ingredient was applied at a rate of 0.2 lb ai/A/application with a rotary spreader. TTR samples were collected before and after each application; 7 and 14 days after the first and second application; and at 4 and 12 hours, and 1, 2, 4, 7, 10, 14, 21, 28, and 35 days after

the third (last) application. Two control samples were collected at each sampling interval from the untreated plot. The samples were collected using the modified California Roller technique. TTR residues were below the LOD ($0.001 \mu\text{g}/\text{cm}^2$) at all sampling intervals except the sampling event immediately after the third (last) application, 0DAT3. At 0DAT3, 4 of the 9 samples collected had detectable residues ($>\text{LOD}$) but all were below the LOQ ($0.005 \mu\text{g}/\text{cm}^2$); the average TTR residue for 0DAT3 was $0.0014 \mu\text{g}/\text{cm}^2$ (0.06% of the application rate). Since all residues were below the LOD or LOQ, residue decline could not be assessed and dissipation curves to calculate half-lives could not be generated. A summary of the results is provided below in Table G.2. The measured 0DAT3 residue value of $0.0014 \mu\text{g}/\text{cm}^2$ was used to estimate risk on turf from granular formulations.

Statistic	Talsar® PL Granular Insecticide (Fresno, California)		
	1DAT1 - 14 DAT2	0DAT3	4hrDAT3-12hrDAT3
Application Rate (lb ai/A)	0.2 lb ai/A/application		
Measured Average Residue ($\mu\text{g}/\text{cm}^2$)	$<\text{LOD}^1$	0.0014	$<\text{LOD}^1$

1. All residues were less than the limit of detection (LOD; $0.001 \mu\text{g}/\text{cm}^2$).

- 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 42142201), roses and chrysanthemums (MRID 44955201), and strawberries (MRID 44684401). 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 $0.598 \mu\text{g}/\text{cm}^2$ immediately after the third application (0DAT3) and increased to $0.753 \mu\text{g}/\text{cm}^2$ at 1DAT. Average residues declined to $0.0248 \mu\text{g}/\text{cm}^2$ by the last sampling interval (35DAT3). The data and the results of the pseudo-first order statistical analysis are summarized below in Table G.3. The predicted DAT0 residue value of $0.537 \mu\text{g}/\text{cm}^2$ 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.

Location	California
Half-life (days)	7.2
R ²	0.9382
Decay Constant (k)	-0.096
Daily Dissipation (%)	9
Actual Average 0DAT3 ($\mu\text{g}/\text{cm}^2$)	0.598
Predicted Initial Residue (C_0) ($\mu\text{g}/\text{cm}^2$)	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 (C. Smith, D390098, 09/15/2011). 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.