

HUMAN PESTICIDE EXPOSURE ASSESSMENT
(For Section 3 New Product/Use Registration)

BIFENTHRIN
(Biflex™ TC Used for Subterranean Termite Control)

Michael H. Dong, Ph.D., C.N.S., Staff Toxicologist
Worker Health and Safety Branch
Department of Pesticide Regulation
California Environmental Protection Agency
1020 N Street, Room 200
Sacramento, California 95814-5624

HS-1722 July 14, 1995

ABSTRACT

This pesticide exposure assessment is written to be an integral part of the Department’s risk characterization document for registration of bifenthrin, under the trade name Biflex™ TC, as a subterranean termiticide. Bifenthrin is a pyrethroid compound which has been synthesized for the control of a wide range of foliar insect pests, subterranean termites, and wood-infesting insects. Tremors and tumors are the toxicological endpoints of prime concern for this pyrethroid active ingredient. In this exposure assessment, estimation of the dermal and inhalation exposures for pest control operators was based on a two-part worker exposure study submitted by the registrant. For residents living on treated properties, their inhalation exposures to bifenthrin in indoor air were estimated with data from an air monitoring study, also submitted by the registrant. Biflex TC was used in both studies as a termiticide aqueous emulsion with which bare ground and house foundations located in several states other than California were treated. The absorbed daily dosages calculated from these exposures for the workers and residents varied greatly, ranging downward from 2.6 µg per kilogram of body weight (BW) for applicators to 0.01 µg/kg BW for residents or for service persons working in basements or crawl spaces within a couple of days following termiticide application. Data on bifenthrin metabolism suggest that fecal excretion is the primary route of elimination of unchanged bifenthrin (accounting for a major portion) and the metabolites in rats. The results of other animal studies indicated that the 10-hour dermal absorption of bifenthrin in the rat (and hence presumably in humans as well) was approximately 17.9%
I. INTRODUCTION

Bifenthrin is a pyrethroid compound which has been synthesized for the control of a wide range of foliar insect pests, subterranean termites, and wood-infecting insects. An exposure assessment for this active ingredient (AI) was first performed by the Worker Health and Safety Branch (WH&S) of the California Department of Pesticide Regulation (DPR) in 1991 (Dong et al., 1991). At that time the pyrethroid insecticide was considered under the product trade name Capture® 2EC for use on cotton only. Bifenthrin is now petitioned for registration in California under the trade names Talstar® T&O WSB, Talstar® T&O Flowable, and Biflex® TC. To facilitate the discussion, the exposure assessment for the Talstar products, which are to be used on greenhouse-grown ornamentals, is presented in a separate document. The present document contains only the exposure assessment for Biflex TC, which is to be used for control of subterranean termites. This Biflex TC exposure assessment is hence written to be an integral part of the Department’s risk characterization document for use of bifenthrin as a termiticide under the new use request. Results and information contained in this Biflex TC exposure assessment document may also be used as the starting point for developing mitigation measures if exposure to the pesticide is found to cause excessive risk. The toxicological endpoints of prime concern for bifenthrin are tremors and tumors (Reed, 1991).

II. PHYSICAL AND CHEMICAL PROPERTIES

Bifenthrin (Talstar®, Brigade®, Biflex®, Capture®, 2-methyl[1,1’-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-tri-fluoro-1-propenyl)-2,2-dimethyl-cyclopropanecarboxylate, CAS No. 82657-04-3, molecular formula C$_{23}$H$_{22}$ClF$_{3}$O$_{2}$, molecular weight 422.88) belongs to the synthetic pyrethroid
family and is a non-corrosive substance. It is commercially available as a viscous oil which hardens to a solid, light brown mass. The vapor pressure of bifenthrin is $1.81 \times 10^{-7}$ torr at 25°C, with a specific gravity of 1.21 at 25°C and a melting point of 68-70.6°C. Although bifenthrin has very low solubility in water (0.1 mg/L), it is readily soluble in acetone, chloroform, dichloromethane, diethyl ether, and toluene (FMC, 1984). The following is the chemical structure of bifenthrin:

III. U. S. EPA/CALIFORNIA STATUS

Bifenthrin was used experimentally on cotton in the United States as early as 1985 under a one-year Experimental Use Permit (EUP) issued by the U. S. Environmental Protection Agency (USEPA), which also approved the temporary tolerance of the active ingredient in or on cottonseed at 0.5 ppm (parts per million). The temporary tolerance was issued to permit the marketing of cottonseed under the terms and conditions that were set forth in the EUP.

USEPA later extended the use of bifenthrin on cotton under a Conditional Registration issued in 1988 with a final expiration date of October 31, 1991, and announced its formal ruling on the aforesaid tolerance (USEPA, 1988). The tolerance levels of bifenthrin from that formal ruling remained the same as before but with an expiration date of October 31, 1992. In that 1988 issuance, USEPA further concluded that the proposed use of bifenthrin on cotton would pose extremely small risks to humans, but nonetheless classified the insecticide as a Category C (possible human) oncogen. The basis of their oncogen classification was the observation that there was a statistically significant increase in leiomyosarcoma (a type of tumor) incidence in the male mouse urinary bladder.

Since 1991, bifenthrin has also been registered for use on cotton in California. In addition, between 1992 and 1994 a number of SLN (Special Local Needs) were issued in California for bifenthrin used on other crops (e.g., broccoli, lettuce, and cabbage).

IV. FORMULATION/INTENDED USE PATTERN

All pesticides containing bifenthrin as the active ingredient are manufactured solely by the FMC Corporation. These bifenthrin products are either federally registered or pending federal registration, and are all made available under the trade name Talstar®, Brigade®, Biflex®, or Capture®. Early on, the technical grade bifenthrin was known by the code number FMC 54800. This active ingredient is now available in five marketing formulations: an EC (emulsifiable concentrate), a WP (wettable powder), a WSB (water-soluble bag), a flowable, and a TC
Capture 2EC (EPA Reg. No. 279-3069) is registered in California (as well as federally registered) for use on cotton only. Talstar 10WP (EPA Reg. No. 279-3057) and Talstar WSB (EPA Reg. No. 279-3086, 279-3087) are only federally registered for greenhouse-grown ornamentals. Talstar 2EC (EPA Reg. No. 279-3056), which has the exact same technical formulation as Capture 2EC, is also only federally registered for greenhouse uses. Biflex TC also has the exact same technical formulation as Capture 2EC or Talstar 2EC, and is federally registered for subterranean termite control. According to FMC, Brigade 10WP and Brigade WSB have been submitted to USEPA for registrations on strawberries, walnuts, pears, and pecans. Although registrations of the Brigade products are still pending, federal EUP programs for them are presently in place.

Currently, the only bifenthrin labels under review by DPR are those for use of Talstar T&O (EPA Reg. No. 279-3087 and 279-3105) on greenhouse-grown ornamentals and for use of Biflex TC (EPA Reg. No. 279-3112) as a subterranean termicide. Like Capture 2EC, each gallon of the Biflex TC product contains 2 lb of the active ingredient. The label for the Biflex TC product specifies that a maximum of 4 qt AI per 100 gallons of water, or 0.24% AI in emulsion, be applied to control subterranean termites. It is recommended that 2 to 4 gallons of the emulsion be used per 10 linear feet per foot of depth. Although there is no label restriction for the number of applications to be made per site, it is not common practice for the same site to be treated repeatedly within a short time interval.

V. USAGE IN CALIFORNIA

According to the annual pesticide use report, 1,458 applications of bifenthrin were made in California in 1991, yielding a total of 10,513 pounds of the active ingredient used in that year (DPR, 1993). In 1992, the second year after bifenthrin was registered in California (for use on cotton only), the number of applications and the annual poundage were increased to 10,584 and 71,817, respectively (DPR, 1994a). These 1992 figures decreased slightly (3% and 10%, respectively) in 1993 (DPR, 1995). (Later statistics are not yet available to WH&S, as they are currently being compiled and verified.)

VI. LABEL PRECAUTIONS

Like Capture 2EC, Biflex TC is labeled as a Toxicity Category II (Warning), federally restricted use pesticide. Its bifenthrin active ingredient is also classified by USEPA as a Category C oncogen, as noted in Section III. The product label requires that applicators wear long sleeved shirt and trousers (fabric not specified). The label also specifies that mixer/loaders wear similar protective clothing plus chemical-resistant gloves and goggles (or a face shield). There is no
reentry interval restriction for residents entering treated areas.

The statement of practical treatment advises that no vomiting be induced if the victim accidentally swallows the product. For eye or dermal contact, the label recommends flushing with plenty of water. If poisoning is through inhalation, the victim needs to be immediately removed from the contaminated atmosphere and, if necessary, to be given artificial respiration. In all cases, medical attention should be sought as soon as possible.

VII. WORKER ILLNESSES

There were no illnesses or injuries reported by California physicians in 1991 as related to the use of bifenthrin (DPR 1994b). Two illness reports associated with the use of this active ingredient were filed in 1992, however, one being a possible case of systemic illness and the other a possible case of skin irritation (DPR, 1994c). (Later statistics are not yet available to WH&S, as they are currently being compiled and verified.)

VIII. ACUTE DERMAL AND RELATED TOXICITY

Insofar as Biflex TC has the exact same technical formulation as Capture 2EC, the results of the acute toxicity studies submitted earlier for Capture 2EC should be deemed the same as for Biflex TC. According to a review by the Medical Toxicology Branch (Duncan, 1992), the dermal LD$_{50}$ of Capture 2EC was shown in an acute toxicity study (FMC, 1985a) to be greater than 2,000 mg/kg (Category III toxicity) for both male and female rabbits. Another acute study submitted by the registrant (FMC, 1985b) showed that Capture 2EC was non-irritating to either abraded or intact skin of the rabbit and the pesticide hence was classified as having very low (Category IV) toxicity for primary skin irritation. The review further indicated that the positive (Category III) acute effects seen in rabbits in an eye irritation study (FMC, 1985c) were cleared by 24 h.

In addition, a skin sensitization study (FMC, 1985d) was submitted from which Capture 2EC (and hence Biflex TC as well) was judged to be a sensitizer to guinea pigs. Some details of this study can be found in an earlier exposure assessment for use of bifenthrin on cotton (Dong et al., 1991). In spite of this observation, no sensitization statement is specified on the product label.

IX. DERMAL ABSORPTION

A dermal absorption study was submitted for evaluation in 1989 (LeVan, 1989), in support of the results of an earlier study submitted in 1986 (Craine, 1986). In the 1986 study, approximately 50% of the applied dose was found bound to the treated skin at all dose levels ranging from 50 - 5,000 mg per rat (or per 12.5 cm$^2$ skin area); the test animals and the controls were observed for 24 h or less. The registrant then conducted another study with an extended observation period in order to comply with the USEPA guidelines published then (Zendzian, 1989) regarding the high
percent residues that were found in the treated skin. This effort led to the submission of the 1989 supplemental study, in which the lowest (practical) dose (i.e., 0.05 mg per 12.5 cm$^2$) from the first study was applied to 36 Charles River male CD rats.

The recovery of $^{14}$C from all sources in the 1989 supplemental study was found unacceptably low, however, ranging from 55 - 68%. In light of this low recovery of radioactivity, WH&S made a recommendation to the registrant that a more acceptable study be conducted which should be similar in design to the earlier ones but with higher dose recovery (Thongsinthusak, 1989). That recommendation resulted in the submission of yet another study on dermal absorption of bifenthrin in the rat (Braun, 1990), which was later concluded by WH&S to be acceptable (Thongsinthusak, 1990). The 10-hour dermal absorption for bifenthrin calculated from this third study was determined to be approximately 17.9% of the total dose administered. As shown later, the dermal absorption rate determined from this third study was used in the present (and previous) worker exposure assessment.

X. ANIMAL METABOLISM

A series of nine metabolism studies were submitted for evaluation. In all of these studies, the biologic fate of bifenthrin was investigated in rats only. The Medical Toxicology Branch has given an extensive review of these studies and has found them all individually unacceptable (Morgan, 1989). That review has nonetheless concluded that as a group, these rat studies provide sufficient information to fulfill the metabolism data requirements. A brief review of each of these nine studies can be found in the earlier worker exposure assessment for use of bifenthrin on cotton (Dong et al., 1991). On the next page in Figure 1 is an abridged version of the metabolic pathway of bifenthrin in rats proposed by El-Naggar and Wu (1986), who were the investigators of the fourth study of this series of animal metabolism studies. Note that for simplicity, only the major (with amount $\geq$ 5% of the applied dose) metabolites are included in Figure 1.

XI. EXPOSURE ASSESSMENT

Two work groups are of main concern in the assessment of occupational exposure to bifenthrin used for control of subterranean termites and wood-infesting insects. Workers may be exposed to bifenthrin when they mix/load the termiticide/insecticide or apply it at the target sites. Also, residents including service persons hired by them (to work inside their house) may be potentially exposed to indoor air particulates of bifenthrin that has been applied to their house foundation.

The worker and human exposures to bifenthrin calculated here, as summarized in Table 1, were from a two-part worker exposure study (McCarty et al., 1992) and an air monitoring study (Javick and Wright, 1991) submitted by FMC. In both of these studies, bifenthrin was used as a
Figure 1. Major Metabolic Pathway of Bifenthrin in Rats (Adopted from El-Naggar and Wu, 1986)
Table 1. Daily Exposure and Absorbed Dosage for Workers Handling Bifenthrin\(^a\) and for Residents Living on Treated Properties\(^b\)

<table>
<thead>
<tr>
<th>Job Class/Residents</th>
<th>Dermal Exposure (mg/person/day)(^c)</th>
<th>Inhalation Exposure (µg/person/day)(^d)</th>
<th>Absorbed Dosage (µg/kg BW/day)(^e)</th>
<th>Annualized Dosage (µg/kg BW/day)(^f)</th>
<th>Lifetime Dosage (µg/kg BW/day)(^g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicators</td>
<td>1.18 (2.53)</td>
<td>1.53 (3.75)</td>
<td>2.55 (6.97)</td>
<td>1.53 (4.18)</td>
<td>0.82 (2.23)</td>
</tr>
<tr>
<td>Mixer/Loaders</td>
<td>0.78 (3.96)</td>
<td>0.90 (2.94)</td>
<td>1.59 (8.50)</td>
<td>0.95 (5.10)</td>
<td>0.51 (2.72)</td>
</tr>
<tr>
<td>M/L/Applicators</td>
<td>0.98 (3.25)</td>
<td>1.22 (3.35)</td>
<td>2.07 (7.74)</td>
<td>1.24 (4.64)</td>
<td>0.66 (2.47)</td>
</tr>
<tr>
<td>Residents</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basement</td>
<td>1.00 (7.56)</td>
<td>0.01 (0.06)</td>
<td>≤ 3.3 x 10(^{-4})</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living Areas</td>
<td>0.63 (5.99)</td>
<td>0.02 (0.15)</td>
<td>≤ 8.2 x 10(^{-4})</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combined(^h)</td>
<td>1.59 (13.1)</td>
<td>0.01 (0.10)</td>
<td>≤ 5.0 x 10(^{-4})</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) for workers at post-construction sites with personal protective equipment as specified on the product label.

\(^b\) including service persons who are required to do repair work in the basement or crawl space.

\(^c\) based on the arithmetic mean (and the highest) exposure rates presented in Tables 2 and 3 below for post-construction workers (under the assumption that workers would handle 3 lb of the active ingredient in an 8-hour work day); for pesticide control operators who handle Biflex TC single-handedly, their daily exposure is the average of those estimated for mixer/loaders and for applicators.

\(^d\) see footnote \(^c\) above for pest control operators; for residents, based on the arithmetic mean (and the highest) exposure rates (per person basis) presented in Table 4 below.

\(^e\) based on a dermal absorption of 17.9\% (see Section IX), on a default inhalation absorption of 50\% (WH&S Exposure Assessment Group, 1993), and on individual body weight (BW) observed in the FMC study (McCarty et al., 1992) for applicators (mean = 83.0 kg) and mixer/loaders (mean = 84.8 kg); for residents exposed to bifenthrin in the living areas, the average body weight of 19.7 kg was used since a male child of age 6 has the highest ratio of respiration rate to body weight; for residents exposed to bifenthrin while doing repair work or the like in the basement, the average male/female body weight of 68.7 kg was used.

\(^f\) based on three-fifths of the base period (i.e., 219 days per year) for pesticide control operators; on the other hand, the annualized exposure to bifenthrin from Biflex TC for residents was expected not to occur more than 2 days per year (see text for discussion), in accordance with the assumption made in an earlier exposure assessment by Brodberg (1990) for isofenphos also used as a termicide.

\(^g\) based on the assumption that a worker would handle the same chemical for 40 years during his or her lifetime (75 years); lifetime exposure to bifenthrin from Biflex TC applications is not supposed to occur for residents whose properties are not expected to be treated repeatedly for any number of years.

\(^h\) based on the assumption that an adult resident would spend the remaining 16 h inside the house (in the living area) after working in the basement or crawl space for 8 h, and on a default respiration rate of 9 L/min (0.54 m\(^3\)/h) for this age group under resting activities during these remaining 16 h (WH&S Exposure Assessment Group, 1993; USEPA, 1990).
subterranean termiticide to treat bare ground and house foundations located in several states other than California. Worker exposure to bifenthrin used for control of wood-infesting insects was not included in this assessment based on the reasonable presumption that this type of exposure is not supposed to be any greater than that from applying bifenthrin as a subterranean termiticide. According to the label, the application rates and methods for treatment of wood-infesting insects or other pests with Biflex TC are not any greater or any more complicated than those for applying the product as a subterranean termiticide. Note that much of the Biflex TC use for wood treatment is to be in localized areas, which are part of the house structures and hence are inaccessible to people later on. Also, in some cases paint-on or low-pressure spray applications may be used for the control of wood infesting insects. These types of application are not used in soil treatment, and are not supposed to yield any greater exposure potential because of the low pressure involved. Because the product is to be used as a subterranean termiticide or a wood-infesting insecticide, there also should be no foliar bifenthrin dislodgeables which any worker or resident would be exposed to.

As shown in Table 1, the average daily dosages calculated from dermal and inhalation exposures for workers handling Biflex TC and for residents living on treated properties varied greatly, ranging downward from 2.6 µg per kilogram of body weight (BW) for applicators to 0.01 µg/kg BW for residents or for service persons working in basements or crawl spaces within a day or two following termiticide application. Calculations of the dermal and/or inhalation exposures for these various individuals are described in the subsections below. In this assessment, the amount of active ingredient that a worker would handle in a normal 8-hour work day was assumed to be 3 lb. This assumption is considered reasonable in that approximately 2 to 3 h were required for handling 1 lb of the bifenthrin active ingredient (see Tables 2 and 3 below). Some of the treatments were seen to have lasted more than 7 h and to have used up to 3 lb of the active ingredient. In the biological monitoring study by Gibbons et al. (1993) for chlorpyrifos used as a structural pest control insecticide, those pest control operators were also seen to have worked 8 h (including travel to and from the job sites) on an average day.

Note that in the exposure and air monitoring studies cited above, the investigators promoted the use of geometric means as the point estimates of worker exposure or air level. Their argument for this use was the recommendation made by the National Institute for Occupational Safety and Health (Leidel et al., 1977) that the geometric mean be used for this type of calculation. Although WH&S frequently makes use of the geometric mean, there are at least two reasons for presenting only the arithmetic means and the highest measured values in Table 1. First, statistical tests showed that not all of the dermal or inhalation exposures measured in the FMC studies had a lognormal rather than a normal distribution. Second, the exposure data collected by FMC were not from the same or a similar field study, in that the pre- or post-construction treatments with Biflex TC were actually on different days, in different parts of the country with likely different environmental parameters, for different types of constructions, and using different application methods. In short, it is debatable whether the single measurements from these individual treatments (that were different with respect to time, place, and equipment type) could be
considered as replicates that are seen in a typical field study. At any rate, the arithmetic means were presented in Table 1 merely as a convenient way of providing a central tendency or point estimate without necessarily implying that the data tended to have a normal distribution.

XI.1 Applicators and Mixer/Loaders
For workers spraying Biflex TC emulsion for bare ground (pre-construction areas) and house (post-construction areas) treatments, estimation of their dermal and inhalation exposures was based on a two-part study submitted by FMC (McCarty et al., 1992). In this study, dermal and inhalation exposures were monitored during mixing and application of the termiticide Biflex TC at pre- and post-construction sites located in several states. Biflex TC was used at these sites as a dilute aqueous emulsion with a target concentration of the bifenthrin active ingredient set at 0.125%. The post-construction sites included 17 houses located in Delaware, Florida, New Jersey, and Pennsylvania, whereas the sites for pre-construction treatment consisted of 11 plots located in Georgia, Illinois, and New Jersey. According to the study report, the mixing/loading and application work in all cases were done by commercial, licensed pest control operators using practices and equipment representative of termiticide uses throughout the country.

For the pre-construction phase, plots of bare soil measuring 1,000, 2,000, or 3,000 sq ft were used to simulate slab sites. At these pre-construction sites, the termiticide aqueous emulsion was applied to soil using a coarse spray. The tasks involved for the preparation of post-construction treatment were comparatively more extensive and intensive. They included drilling, trenching, or filling holes. In most cases, either a long or short soil rod was used to treat the trenches around the perimeter of the house. Basements and crawl spaces were generally treated with injection rods or probes. The specifics varied depending on the type of construction involved and on the company that did the treatment.

The sampling media included socks and a union suit (top and pants) that were worn underneath normal work clothes which included pants, socks, and typically either a short-sleeved shirt with coveralls or a long-sleeved shirt. Also used as collection media were patches placed on the upper back, chest, and hat, water and detergent hand rinses, and air samples collected on glass fiber filters mounted in cassettes using air pumps set at a flow rate of 2 L/min. For each replicate (measurement), two workers were monitored for one day or as long as the treatment lasted. One worker did all of the mixing and loading using open pour methods, while the other did all of the application task. Other tasks were done by either worker. During mixing, chemical-resistant gloves were worn and most mixer/loaders also wore goggles or a face shield. Some workers also wore chemical-resistant or cotton gloves during applications.

Dermal exposures other than hands were calculated in the study by summing the total bifenthrin measured in the union suit (top and pants) and socks and by extrapolating from the patch dosimeters to standard body surface areas of the face and neck. Hand exposure was measured using both the one-minute water wash and the detergent wash that followed. It is of note here that on the whole, the clothing dosimetry as used in the FMC study tended to overestimate the
actual dermal exposure somewhat. In real life workers are expected to wear a tee-shirt underneath a long-sleeved shirt, the latter is required by the label. Yet in the study many workers wore the union suit top (the sampling medium) directly underneath a long-sleeved shirt without coveralls. On the other hand, the filter effect of the short-sleeved shirt worn underneath the coveralls by some workers is not expected to be any more than that of the tee-shirt worn underneath a long-sleeved shirt.

Potential inhalation exposure was calculated from the flow rate of the air pumps and a respiration rate of 29 L/min for adults engaged in light work activities. In this exposure assessment, a respiration rate of 14 L/min was used for light work as this is now common practice within WH&S (WH&S Exposure Assessment Group, 1993).

Tables 2 and 3 summarize the dermal and potential inhalation exposures for applicators and for mixer/loaders working with Biflex TC, respectively. Measured residues were adjusted for the mean recoveries of bifenthrin from the various monitoring media fortified in the field (with formulation diluted with water from the site). The mean recoveries from all monitoring media were found to range acceptably from 71 to 123%.

In recent years there have been only a few other exposure assessments performed by WH&S for active ingredients used as soil termiticides, which potentially involved application methods, protocols, and professional training that are similar as a group (relatively speaking or at least superficially). This unique similarity in itself thus warrants a comparison of the worker exposures calculated for Biflex TC and for these few other similar pesticides. Daily dermal and inhalation exposures were calculated earlier by Brodberg (1990) and by Thongsinthusak et al. (1993) in their exposure assessments for isofenphos and for chlorpyrifos, respectively, that also were used as a soil termiticide. An average daily dermal exposure of 16.5 mg/worker and an average daily inhalation exposure of 0.13 mg/worker were calculated by Thongsinthusak et al. for workers who mixed, loaded, and applied chlorpyrifos single-handedly. For mixer/loader/applicators handling isofenphos, average daily dermal and inhalation exposures were estimated by Brodberg to range from 5.45 mg/worker to 26.67 mg/worker and from 10 µg/worker to 50 µg/worker, respectively, depending on the type of location treated (e.g., slab, basement, crawl space, etc.). The exposures to bifenthrin presented in Table 1 were found to be comparable (within a few fold difference) to these earlier estimates. Although the exposures to isofenphos and to chlorpyrifos calculated earlier were several times higher, the amount of these active ingredients in their termiticide aqueous emulsion used was also several times greater. Note that a respiration rate of 29 L/min was assumed for light work in the earlier exposure assessments.
Table 2. Daily Exposure and Absorbed Dosage for Applicators Handling Bifenthrin\(^a\)

<table>
<thead>
<tr>
<th>Treatment Type BW/day(^e,f)</th>
<th>lb A.I.(^b) Handled</th>
<th>Hours Worked</th>
<th>Exposure (µg/lb A.I. handled)</th>
<th>Absorbed Dosage (µg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal(^c)</td>
<td>Inhalation(^d)</td>
</tr>
<tr>
<td><strong>Pre-Construction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>range (n = 11)</td>
<td>1.00 – 3.00</td>
<td>0.92 – 4.43</td>
<td>0.1 – 21.6</td>
<td>0.05 – 0.78</td>
</tr>
<tr>
<td>arithmetic mean</td>
<td>2.27 ± 0.90</td>
<td>2.27 ± 1.10</td>
<td>5.3 ± 7.1</td>
<td>0.24 ± 0.27</td>
</tr>
<tr>
<td>geometric mean</td>
<td></td>
<td></td>
<td>1.9 ± 5.6</td>
<td>0.15 ± 2.53</td>
</tr>
<tr>
<td><strong>Post-Construction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>range (n = 17)</td>
<td>1.00 – 3.00</td>
<td>2.35 – 8.43</td>
<td>29.9 – 842.6</td>
<td>0.03 – 1.25</td>
</tr>
<tr>
<td>arithmetic mean</td>
<td>2.03 ± 0.58</td>
<td>5.48 ± 1.85</td>
<td>392.0 ± 280.9</td>
<td>0.51 ± 0.36</td>
</tr>
<tr>
<td>geometric mean</td>
<td></td>
<td></td>
<td>271.0 ± 2.8</td>
<td>0.31 ± 3.22</td>
</tr>
</tbody>
</table>

\(^a\) based on a worker exposure study submitted by FMC (McCarty et al., 1992) for workers applying Biflex TC at pre- and post-construction sites located in several states other than California.

\(^b\) pounds of bifenthrin active ingredient (A.I.) handled.

\(^c\) including exposures measured with dosimetry on the upper body, the lower body, socks, water wash (from first hand wash), hand wash, the head, and the front and the back of the neck.

\(^d\) based on a respiration rate of 14 L/min (0.84 m\(^3\)/h) for adult males engaged in light work activities, in accordance with recent practice within WH&S (WH&S Exposure Assessment Group, 1993).

\(^e\) based on a dermal absorption of 17.9% (see Section IX), on a default inhalation absorption of 50% (WH&S Exposure Assessment Group, 1993), on 3 lb as the amount of A.I. handled in an 8-hour work day, and on individual body weights (BW) measured in the FMC study for workers at the pre- (mean = 87.2 kg) and post- (mean = 83.0 kg) construction sites, respectively.

\(^f\) calculated with the following equation (for each worker): dosage (µg/kg/day) = ([dermal exposure (µg/lb A.I.) \times 17.9% + inhalation exposure (µg/lb A.I. \times 50%) \times 3 lb/day]) ÷ body weight observed.
Table 3. Daily Exposure and Absorbed Dosage for Mixer/Loaders Handling Bifenthrin

<table>
<thead>
<tr>
<th>Treatment type</th>
<th>lb A.I.$^b$ Handled</th>
<th>Hours Worked</th>
<th>Exposure (µg/lb A.I. handled)</th>
<th>Absorbed Dosage (µg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal$^c$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation$^d$</td>
<td></td>
</tr>
<tr>
<td>Pre-Construction</td>
<td>1.00 − 3.00</td>
<td>0.40 − 4.48</td>
<td>3.3 − 147.9</td>
<td>0.05 − 1.15</td>
</tr>
<tr>
<td></td>
<td>2.27 ± 0.90</td>
<td>2.27 ± 1.17</td>
<td>56.3 ± 50.2</td>
<td>0.22 ± 0.32</td>
</tr>
<tr>
<td></td>
<td>geometric mean</td>
<td></td>
<td>32.6 ± 3.3</td>
<td>0.13 ± 2.46</td>
</tr>
<tr>
<td>Post-Construction</td>
<td>1.00 − 3.00</td>
<td>2.70 − 8.53</td>
<td>10.8 − 1319.3</td>
<td>0.02 − 0.98</td>
</tr>
<tr>
<td></td>
<td>2.03 ± 0.58</td>
<td>5.50 ± 1.81</td>
<td>261.0 ± 409.5</td>
<td>0.30 ± 0.28</td>
</tr>
<tr>
<td></td>
<td>geometric mean</td>
<td></td>
<td>100.0 ± 4.2</td>
<td>0.14 ± 4.03</td>
</tr>
</tbody>
</table>

$^a$ based on a worker exposure study submitted by FMC (McCarty et al., 1992) for workers applying Biflex TC at pre- and post-construction sites located in several states other than California.

$^b$ pounds of bifenthrin active ingredient (A.I.) handled.

$^c$ including exposures measured with dosimetry on the upper body, the lower body, socks, water wash (from first hand wash), hand wash, the head, and the front and the back of the neck.

$^d$ based on a respiration rate of 14 L/min (0.84 m³/h) for adult males engaged in light work activities, in accordance with recent practice within WH&S (WH&S Exposure Assessment Group, 1993).

$^e$ based on a dermal absorption of 17.9% (see Section IX), on a default inhalation absorption of 50% (WH&S Exposure Assessment Group, 1993), on 3 lb as the amount of A.I. handled in an 8-hour work day, and on individual body weights (BW) measured in the FMC study for workers at the pre- (mean = 83.0 kg) and post- (mean = 84.8 kg) construction sites, respectively.

$^f$ calculated with the following equation (for each worker): dosage (µg/kg/day) = \(\frac{\text{[dermal exposure (µg/lb A.I.) x 17.9% + inhalation exposure (µg/lb A.I. x 50%)]} x 3 \text{ lb/day}}{\text{body weight observed.}}\)

In 1993, WH&S staff (Gibbons et al., 1993) conducted a biological monitoring study in which chlorpyrifos was measured in the urine of several pest control operators who used the termiticide for structural pest control. The absorbed daily dosages calculated from exposure to bifenthrin were found to be comparable to those observed in this biological monitoring study. The absorbed dose of chlorpyrifos (equivalent) averaged 111.7 µg per worker per day. This mean estimate was based on application rates ranging from 0.005 to 0.08 lb of the active ingredient per gallon of dilution water (i.e., from 0.06 to 1.0% of chlorpyrifos in aqueous emulsion). It appears at first that after adjustment for application rates, the average daily dosage observed in the biological monitoring study is still several times less than those daily dosages presented in Table 1. However, the dosages for exposure to bifenthrin were calculated from a dermal intake observed in rats, which is expected to be several times greater than that for the same chemical observed in humans.
XI. 2. Residents of Treated Properties

For residents whose properties are treated with Biflex TC termiticide emulsion, the primary concern is their inhalation exposure to indoor air contaminated with bifenthrin particulates (since the vapor concentration in air will be negligible). Estimation of the inhalation exposure for these individuals was based on air samples collected in an air monitoring study by FMC (Javick and Wright, 1991) that involved 15 homes located in Florida, Georgia, New Jersey, and Pennsylvania. At all these homes, the termiticide was used as an aqueous emulsion with a concentration of bifenthrin active ingredient ranging from 0.060 to 0.133%. In addition to air levels of bifenthrin, aromatic levels calculated as xylene arising from the formulation solvent were monitored in at least one room within each of the homes before, during, and after termiticide application.

Air samples for bifenthrin analysis in the study were collected in three or four different locations within the house for 8-hour periods before, during, and at one or more days after termiticide application. The termiticide was applied with the air conditioning or heating system in operation where applicable. All samples were collected in the center of the room at 1 to 5 feet above the floor. Various techniques were used by pest control operators to treat the 15 homes with Biflex TC; these included rodding and trenching outdoors to subslab injection, block void injection, spray application to infested wood, and broadcast application to inaccessible crawl space. The air levels, after adjustment for their mean analytical recovery, are summarized in Table 4. The recoveries of bifenthrin for samples fortified in the field included values lower than normally considered acceptable, with a range from 118 down to 58%. However, the air levels presented in Table 4 were found to be comparable to those indoor air levels of isofenphos reported by Brodberg (1990).

Also included in Table 4 are the inhalation exposures estimated for six-year old children living on treated properties and for adults or service persons who may do repair work in a very confined area closer to the treated foundation, such as the basement or crawl space. A basement may also be used as living quarters in some houses in California. However, those who live in the basement are not expected to stay there all day long, at least not on the day the application is made. As footnoted in the table, the respiration rates for a six-year old child and for an adult or a service person doing an 8-hour repair work were assumed to be 6.5 and 11 L/min, respectively. These assumptions were consistent with common practice within WH&S (WH&S Exposure Assessment Group, 1993) and with the estimates provided in the Exposure Factors Handbook published by USEPA (1990). A six-year old male child was used here for a 24-hour inhalation exposure to indoor bifenthrin primarily because this would give the highest ratio of respiration rate to body weight, thus yielding a more conservative estimate of exposure to indoor air over a 24-hour period for residents of all ages at resting. For purposes of exposure calculation, it is reasonable to assume that a person (regardless of age) will be in the house for 24 h under resting activities even if he or she may be engaged in some light or intensive activities within this time period. This assertion is based on the expectation that an active person will normally stay out(side) of his or her house for at least 6 to 8 h per day. According to a survey by the California Air Resources Board (Phillips et al., 1991), Californians under 12 years of age are likely to spend about 18 h indoors at home. Therefore, a portion of the inhalation exposure to indoor air would
be overestimated from use of the extra hours for resting activities. This extra portion should be sufficient to offset the portion that was underestimated by mistreating the couple of hours of intensive (mostly light) activities as resting activities.

Table 4. Indoor Air Concentration and Exposure to Bifenthrin Particulates in Treated Homes

<table>
<thead>
<tr>
<th>Sampling Location^b</th>
<th>Air Concentration (µg/m^3)</th>
<th>Exposure to Bifenthrin µg/kg BW/day^e</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bifenthrin^c</td>
<td>Aromatics^d</td>
</tr>
<tr>
<td>Basement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>range (n_a = 10; n_b = 10)^f</td>
<td>0.008 – 1.434 0.017 – 22.23 0.001 – 0.110</td>
<td></td>
</tr>
<tr>
<td>arithmetic mean</td>
<td>0.191 ± 0.440 7.505 ± 6.779 0.015 ± 0.034</td>
<td></td>
</tr>
<tr>
<td>geometric mean</td>
<td>0.040 ± 5.876 3.523 ± 7.471 0.003 ± 5.876</td>
<td></td>
</tr>
<tr>
<td>Living Areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>range (n_a = 15; n_b = 9)^f</td>
<td>0.008 – 0.639 0.043 – 13.81 0.004 – 0.304</td>
<td></td>
</tr>
<tr>
<td>arithmetic mean</td>
<td>0.068 ± 0.160 3.406 ± 4.079 0.032 ± 0.076</td>
<td></td>
</tr>
<tr>
<td>geometric mean</td>
<td>0.024 ± 3.399 1.720 ± 4.860 0.012 ± 3.399</td>
<td></td>
</tr>
</tbody>
</table>

^a based on an air monitoring study submitted by FMC (Javick and Wright, 1991) for homes treated with Biflex TC in several states other than California.

^b all samples were collected in center of room at 1 to 5 ft above floor; within the living areas, the maximal sample value usually occurred in the kitchen.

^c based on the maximal sample value measured either during or following treatment; one-half of the detection limit (0.008 µg/m^3) was used for samples with a non-detectable value; nearly 90% of the samples collected on day 2 post-treatment were with a non-detectable value and for the remaining few that were with a detectable value, their value was much below the means presented in this table.

^d based on the maximal sample value measured either during or following termiticide application; the aromatic contents were calculated as xylene.

^e based on a respiration rate of 11 L/min (0.66 m^3/h) for adult males or females who, with an average body weight (BW) of 68.7 kg, may do repair work in the basement for as long as 8 h in one day; and on a respiration rate of 6.5 L/min (0.39 m^3/h) for a six-year old male child who, with an average BW of 19.7 kg (USEPA, 1990), could potentially (but unlikely) be exposed to the indoor air for as long as 24 h in one day (see text for further discussion).

^f n_a = number of air samples collected for aromatic content; n_b = number of air samples collected for bifenthrin content.

In this part of the assessment, the exposure for residents was expected not to occur more than 2 days per year. This expectation was based on the reasonable assumption that the property would not be treated again within a year, and that the very low vapor pressure of bifenthrin would preclude any significant inhalation exposure following deposition. This assumption is consistent with that made earlier by Brodberg (1990) in his exposure assessment for isofenphos used on residential structures. Efficacy data submitted by FMC also showed that Biflex TC had good soil
residuality and a knockdown capability of 1 h even after eight years of storage in an aged soil laboratory termiticide screening trail, which was initiated in 1984 at a USDA forest experiment station (FMC, 1991). There may be residents living in the basement of a treated house, or in some instances the repair work at the basement could last more than two days. However, the air level would likely be negligible after the first day or two since most any air particulates would tend to settle rapidly. This speculation is supported by the data provided in the air monitoring study submitted by FMC. As footnoted in Table 4, nearly 90% of the samples collected at day 2 after treatment were found in the study to be without a detectable value. For the remaining few that were with a detectable value, their value was much lower than the means presented in Table 4. There were a few sites at which additional air samples were collected beyond the first two days after application. These additional samples all showed either a non-detectable value or a value that was very near the detection limit. Lifetime exposure to bifenthrin from Biflex TC applications is not supposed to occur for residents whose properties are not expected to be treated repeatedly over any number of years. The annualized dosages calculated from exposure to bifenthrin in indoor air for residents are presented in Table 1. The air levels of aromatics, the formulation solvent of the bifenthrin active ingredient, are included in Table 4 primarily for background information purposes. To some extent these aromatic contents could be used to reflect the analysis quality of bifenthrin in indoor air, in that a correlation is expected between the air levels monitored for the two chemicals. Simply put, where we found a higher air level of bifenthrin we would also expect to see a higher air level of its aromatic formulation solvent, of which xylene is a part. Table 4 shows that as the mean air level of bifenthrin measured in the basements (as a group) increased two-fold when compared to that measured in the living areas, so did the mean air level of the aromatics measured in the basements when compared to their counterpart measured in the living areas.
XII. REFERENCES


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Duncan R (1992). Data Package Summary and Recommendation Sheet - Bifenthrin (updated from previous reviews by other staff). Medical Toxicology Branch, California Department of Pesticide Regulation (date not given).


