4-12-2000

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

April 12, 2000

SUBJECT: Occupational/Residential Handler and Postapplication Residential/Non-Occupational Risk Assessment for Chlorpyrifos. DP Barcode: D263891. Case No. 818975. PC Code: 059101. Submission: S568580

FROM: Deborah Smegal, M.P.H./Risk Assessor
Re-Registration Branch 3
Health Effects Division (7509C)
Office of Pesticide Programs

and

Timothy Leighton, Environmental Health Scientist
Re-Registration Branch 4
Health Effects Division (7509C)
Office of Pesticide Programs

THRU: Steve Knizner, Branch Senior Scientist
Re-Registration Branch 3
Health Effects Division (7509C)
Office of Pesticide Programs

TO: Mark Hartman
Special Review and Reregistration Division (7508C)
Office of Pesticide Programs

EPA MRID Nos.: 40026001, 40094001, 43013501, 44167101, 44458201, 44444801, 44729401, 44729402, 44589001, 44739301

PHED: Yes, Version 1.1

TABLE OF CONTENTS

1.0 EXECUTIVE SUMMARY 4
2.0 BACKGROUND 11
3.0 OCCUPATIONAL AND RESIDENTIAL EXPOSURE 15
3.1 Handler Exposures & Assumptions 15
Occupational/Residential Handler Exposure/Risk Assessment 18
(1) Indoor Crack and Crevice or Spot Application 18
(2) Broadcast Turf Application (MRID No. 44729401 19
(3) Golf Course Use 22
(4) Application of a Ready-To-Use Formulated Product (MRID No. 44739301) 23
(5) Insecticidal Dust Product Application (Bulbous Duster or Shaker Can) 24
(6) Granular Formulation Application by Hand 25
(7) Loading Granular Formulation and Applying with Belly-Grinder Equipment 26
(8) Loading Granular Formulation and Applying with a Push-Type Spreader 26
(9) Pre-Construction Termiticide Use for Subterranean Termite Control (Mixing/Loading and Applying) (MRID No. 44589001) 27
(10) Post Construction Termiticide Use (Mixing/Loading and Applying) for Subterranean Termite Control (MRID No. 44729402) 28
(11) Paintbrush Application 30
(12) Ornamental Application 31
(13) Mosquitocide Mixer/Loader/Applicator 31
3.2 Residential/Worker Postapplication Exposures & Assumptions 32
3.2.1 INDOOR POSTAPPLICATION EXPOSURES. 33
(1) Crack, Crevice and Spot Treatment of Kitchen and Bathroom (MRID 44458201) (Inhalation Exposures in a Treated Room) 33
(2) Crack and Crevice Treatment of Other Rooms Using Residential SOPs (Dermal and Oral Exposures in an Untreated Room) 35
(3) Pet Collar Uses 37
(4) Residential Treatment for Subterranean Termite Control (MRID No. 40094001) 38
(5) Insecticidal Dust Products 39
3.2.2 OUTDOOR POSTAPPLICATION EXPOSURES 40
(6) Lawn Treatment using a Liquid Spray (MRID No. 43013501) 40
(7) Lawn Treatment using a Granular Product (MRID No. 44167101) 40
(8) Golf Course Uses 41
(9) Mosquitocide Uses 42
(10) Yard and Ornamental Sprays 43
(11) Perimeter Treatment of Residences 44
3.2.3 SCIENTIFIC LITERATURE 44
4.0 OCCUPATIONAL AND RESIDENTIAL RISK CHARACTERIZATION 47
4.1 Risk and Uncertainty Characterization of Handler Exposures 47
(1) Indoor Crack and Crevice Treatment. 47

(2) Broadcast Turf Applications 48
(3) Golf Course Use. 49
(4) Ready-to-Use Formulated Product. 50
(5) Insecticidal Dust Products. 50
(6) Granular Formulation by Hand. 51
(7) Granular Formulation Application with Belly Grinder. 51
(8) Granular Formulation Application with Push-type Spreader. 51
(9) Pre-Construction Termiticide Treatment. 51
(10) Post-Construction Termiticide Treatment. 52
(11) Paint Brush Applications. 52
(12) Ornamental Application. 52
(13) Mosquitocide Mixer/Loader/Applicator 53
4.2 Risk and Uncertainty Characterization of Postapplication Exposures 53
(1) Crack and Crevice Treatment of Kitchen and Bathroom (Inhalation Exposure for Treated Rooms). 54
(2) Crack and Crevice Treatment of Other Rooms (Dermal and Oral Exposure in Untreated Rooms). 55
(3) Pet Collar Uses. 55
(4) Termiticide Treatment. 56
(5) Insecticidal Dust Treatment. 57
(6) Lawn Treatment with a Liquid Spray. 57
(7) Lawn Treatment with a Granular Insecticide. 57
(8) Golf Course Use. 58
(9) Mosquitocide Use. 58
(10) Yard and Ornamental Spray Treatment. 59
(11) Perimeter Treatment of Residences. 59
5.0 DATA NEEDS 75
6.0 REFERENCES 76

1.0 EXECUTIVE SUMMARY

This document contains the occupational and residential exposure assessment for chlorpyrifos, resulting from the residential uses of chlorpyrifos products. Exposures are evaluated for occupationally-exposed Pest Control Operators (PCOs) and Lawn Care Operators (LCOs) at residential sites, residents who apply chlorpyrifos products, and residential populations that may be exposed following pesticide application. Some products containing chlorpyrifos are intended primarily for homeowner use, while some are intended primarily or solely for PCO/LCO use. This memorandum addresses non-agricultural uses, focusing on residential sites. Agricultural, ornamental and animal premise uses are addressed elsewhere (memorandum from T. Leighton to D. Smegal, DP Barcode D263893, April 2000).

Chlorpyrifos is an organophosphate insecticide used extensively in residential settings by both residents and PCOs. Chlorpyrifos' most common trade names are Dursban, Empire 20, Equity, and Whitmire PT 270. It is one of the top five insecticides used in residential settings. There are approximately 822 registered products containing chlorpyrifos on the market (REFs 9/14/99). Registered uses include a wide variety of food, turf and ornamental plants, as well as indoor product use, structural pest control, and in pet collars. It is used in residential and commercial buildings, schools, daycare centers, hotels, restaurants, hospitals, stores, warehouses, food manufacturing plants and vehicles. In addition, it is used as an adult mosquitocide. In 1998, Dow AgroSciences (DAS) estimated that 70% of the urban chlorpryifos use involved termite control. Approximately 11 million pounds are applied annually in non-agricultural settings (i.e., residences, schools, golf courses, parks) in the U.S.

In June 1997, the registrants of chlorpyrifos voluntarily agreed to measures designed to reduce household exposure to chlorpyrifos, as part of a Risk Reduction Plan. This voluntary plan involved deletion of: indoor broadcast use, use as an additive to paint, direct application to pets (sprays, shampoos and dips), and indoor total-release foggers. The technical chlorpyrifos products have been amended to reflect the negotiated plan. The technical label limits end use product labeling to only those sites which are specified on its label. In addition, as part of this agreement, the registrants agreed to work with EPA to develop policies for a number of areas including:

- limiting household consumer use to only products packaged as ready-to-use;
- prohibiting use in inappropriate areas (e.g., toys, drapes, furniture);
- requiring PCOs to clean up spills and misapplications;
- requiring more training of PCOs and more supervision during application;
- reducing exposure by eliminating concentrates which require mixing;
- establishing specific protection measures for humans and pets during and immediately after application;
- revising labels to include appropriate intervals between treatment (e.g., to replace "use as necessary", currently on some labels);
- revising labels for safer termiticide and pet care products per PR notice 96-7 on all termiticide labeling and 96-6 on all pet care product labeling and support the Agency

efforts to expedite these changes for other products; and

- accelerate education and training for PCOs on these measures to reduce risk and exposure, label improvements, and implementation of recent PR Notices 96-7 (for termiticides) and 96-6 (for pet care products), and support the Agency efforts to expedite these changes for other products.

Chlorpyrifos, O,O-diethyl O-(3,5,6-trichloro-2-pyridyl) phosphorothioate, is an insecticide formulated as a wettable powder (containing 50% a.i.), emulsifiable concentrates (41.5-47%), dust (containing 0.1-7% a.i.), granular (containing 0.075%-2.5% a.i.), bait (containing 0.5% a.i.), flowables (containing 30% a.i.), impregnated material (containing 0.5-10% a.i.), pelleted/tableted (containing 0.5-1.0% a.i.), pressurized liquids (0.9-3.8% a.i.), and microencapsulated (0.5-20% a.i.). According to DAS, wettable powders packaged in open bags and dry flowables are no longer available and are being removed from active registrations. They are not assessed in this chapter and are no longer eligible for re-registration. The Agency will work with DAS to delete any other formulations and/or products that are obsolete.

Dow AgroSciences' states that formulations with concentrations greater than one pound a.i. per gallon (approximately 13% a.i.) are sold only to pest control or turf and ornamental professionals. Lower concentrations are available to homeowners from other suppliers for over-the-counter purchase. Except aerosols, granules and dusts, all formulated end-use products for application are diluted in water to a concentration of 1 percent a.i. or less (Dow AgroSciences 1998). However, HED is aware of at least one company that sells concentrated chlorpyrifos products (i.e., >13% up to 44.8% a.i.) to the public on the Internet (www.ADDR.com\~pestdepo\gizhome.html) as of March 1, 2000.

The toxicity endpoints used in this document to assess hazards include short-, intermediate- and long-term dermal and inhalation endpoints, and the acute oral endpoint. A route-specific short-term dermal no-observed adverse effect level (NOAEL) of 5 mg/kg/day from a 21-day dermal rat study has been identified based on plasma and red blood cell (RBC) cholinesterase (ChE) inhibition of 45% and 16%, respectively at 10 mg/kg/day (the lowest observed adverse effect level, LOAEL). Therefore, a dermal absorption adjustment is not necessary. The intermediate- and long-term dermal NOAEL is converted from an oral NOAEL of 0.03 mg/kg/day from a weight of the evidence from 5 oral studies in dogs and rats using a 3 percent dermal absorption factor. Plasma and RBC ChE inhibition occurred in these studies at dose levels of 0.22 to 0.3 mg/kg/day. Dermal absorption was estimated to be 3 percent based on the ratio of the oral lowest-observed-adverse effect level (LOAEL) of 0.3 mg/kg/day from the rat developmental neurotoxicity study (MRID Nos. 44556901, 44661001) to the dermal LOAEL of 10 mg/kg/day from the 21-day dermal study (MRID No. 40972801) for plasma and red blood cell cholinesterase inhibition. This absorption factor is comparable to the dermal absorption estimated from human data of 1-3% (MRID No. 00249203).

The short- and intermediate-term inhalation NOAEL is 0.1 mg/kg/day from two separate 90-day rat inhalation studies that did not observe effects at the highest dose tested. At higher oral doses of 0.3 mg/kg/day(LOAEL), 43% plasma and 41% RBC ChE were observed in animals. The

lung absorption is assumed to be 100 percent of oral absorption. The long-term inhalation NOAEL is converted from an oral NOAEL of 0.03 mg/kg/day from the 5 oral studies in dogs and rats, assuming that inhalation and oral absorption are equivalent. The acute oral NOAEL is 0.5 mg/kg/day from an acute oral rat study that observed 28-40% plasma cholinesterase inhibition 3-6 hours after dosing male rats with a single dose of 1 mg/kg/day (memorandum from D. Smegal to S. Knizner, April 6, 2000, HED Doc number 014088). The acute oral NOAEL was used to assess short-term exposures resulting from incidental ingestion (i.e., hand to mouth exposures) of less than one week for children. This is considered appropriate because exposures and risks are calculated for the day of application, when residential exposures are expected to be greatest. Oral exposure was not evaluated for workers. The exposure duration for short-term assessments is 1 to 30 days. Intermediate-term durations are 1 to 6 months, and long-term exposures are durations greater than six months.

For the dermal and inhalation risk assessments, risk estimates are expressed in terms of the Margin of Exposure (MOE), which is the ratio of the NOAEL selected for the risk assessment to the exposure. For occupationally exposed workers, MOEs > 100 (i.e., 10x uncertainty factor for interspecies extrapolation and 10x uncertainty factor for intraspecies variability) do not exceed HED's level of concern. For residential populations, MOEs > 1000, which includes an additional 10x Food Quality Protection Act (FQPA) safety factor do not exceed HED's level of concern. It was assumed that all residential handlers are female.

Multiple exposure studies were conducted by the registrant and submitted to the Agency that evaluate exposures to PCOs/LCOs/residential handlers and residents following application of chlorpyrifos products. These data include biological monitoring, passive dosimetry and environmental measurements. These data, along with supplemental data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, were used to assess potential PCO/LCO exposures resulting from handling and applying chlorpyrifos in residential settings. Postapplication residential exposures were assessed using primarily the registrant-submitted data. In the absence of data, the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 18, 1997), in addition to assumptions for the updated SOPs to be released in 2000, many of which were presented the to the FIFRA Scientific Advisory Panel (SAP) in September 1999, were used to estimate exposures. Exposures associated with all uses of chlorpyrifos products have not been monitored. Therefore, the available data were used to evaluate similar uses (i.e., lawn studies used to evaluate yard and ornamental sprays, residential crack and crevice exposure data used to evaluate similar treatments in other buildings such as schools, day care centers, the workplace, etc).

HED is in the process of revising the residential exposure assessment SOPs. This process may identify specific areas of further concern with respect to chlorpyrifos and exposure to the general population. For example, some of the secondary exposure pathways that EPA will be addressing include exposures resulting from residue tracked into homes from outdoor use, indoor dust, and spray drift. In a recent study, polycyclic aromatic hydrocarbons (PAHs) that are abundant in house dust were shown to increase the toxicity of chlorpyrifos in vitro, particularly at low levels (i.e., 2-50 μM PAHs with 1-180 nM chlorpyrifos-oxon, a metabolite of chlorpyrifos that inhibits

acetyl cholinesterase) (Jett et al. 1999).

HED has concerns for the potential for children's exposure in the home as a result of residential and/or agricultural uses of chlorpyrifos. Environmental concentrations of chlorpyrifos in homes may result from residential uses, spray drift, track-in, or from redistribution of residues brought home on the clothing of farm workers or pesticide applicators. Potential routes of exposure for children may include incidental ingestion and dermal contact with residues on carpets/hard surfaces, in addition to inhalation of vapor and airborne particulates. There are several literature studies that quantify the levels of chlorpyrifos in household dust, indoor and outdoor air, dermal wipe (hands) and soil samples. These residues may persist and the resulting exposures are of a potential chronic nature. Currently, there are no SOPs available to evaluate potential exposures from spray drift and track-in. These scenarios however, may be evaluated in the future pending revisions to the residential SOPs.

As noted previously, there are more than 800 currently registered products containing chlorpyrifos. HED believes the most significant uses and exposures have been evaluated in this assessment. Nevertheless, there is insufficient use information and exposure data to assess exposure resulting from a number of chlorpyrifos uses, including use in vehicles (i.e., planes, trains, automobiles, buses, boats) and other current label uses such as treatment of indoor exposed wood surfaces, supermarkets, restaurants, theaters, playhouses, furniture, and draperies, etc. HED has concern for these and other registered uses based on the scenarios assessed within this document, which show that nearly all the current uses evaluated result in MOEs that exceed HED's level of concern for children and/or adult residents. Therefore, HED requests exposure data for all registered product uses not evaluated in this assessment.

Risk and Uncertainty Characterization

Occupational/Residential Handler Risks

The following scenarios result in MOEs that exceed HED's level of concern (i.e., MOE less than 100 and 1000 for occupational and residential pesticide handlers, respectively):

- Indoor Crack and Crevice Treatment by a PCO and residential applicator;
- Broadcast Turf Treatment by a LCO (intermediate and long-term applicator, mixer/loader) and short-term residential mixer/loader/applicator;
- Spot Treatment of Turf by a residential mixer/loader/applicator;
- Golf Course Treatments by workers (maximum label rate of 4 lb ai/acre for: mixer/loaders of liquids, and mixer/loaders and applicators for greens and tees) and typical and maximum label rates of 1 and 4 lb ai/acre for groundboom applicators);
- Ready-to-Use Formulated product (Ant Stop) containing 0.5% ai chlorpyrifos (residential handler);
- Application of Insecticidal Dust Products by a PCO and residential applicator;
- Application of Granular Formulations by a LCO and residential applicator (by hand, belly grinder or push-type spreader);

- Termiticide Treatments for Pre-Construction by a PCO;
- Termiticide Treatments for Post-Construction by a PCO;
- Paintbrush Applications by a residential applicator;
- Ornamental Application by a residential mixer/loader/applicator, and
- Mosquitocide mixer/loader or applicator for aerial applications of more than 30 days, even with engineering controls

The following scenarios result in MOEs greater than 100 that do not exceed HED's level of concern for occupational pesticide handlers:

- Mixer/loader of liquid lawn care products wearing PPE (LCO)(total MOEs 100-820);
- Golf Course Treatments by workers (typical label rate of 1 lb ai/acre for: mixer/loaders of liquid and wettable powders, and mixer/loaders and applicators for greens and tees; maximum label rate of 4 lb ai/acre for mixer/loaders of wettable powders) (total MOEs 100-400),
- Workers who mix/load or apply chlorpyrifos for aerial mosquitocide applications of less than 30 days with the use of engineering controls (closed systems)(total MOEs 160-240); and
- Workers who mix/load or apply chlorpyrifos for ground-based fogger mosquitocide applications up to several months with the use of PPE and/or engineering controls (total MOEs 100-560).

The results of the PCO/LCO handler assessment in residential/recreational settings for short, intermediate and/or long-term exposure scenarios indicate that most of the MOEs are less than 100, and therefore exceed HED's level of concern. Only the four scenarios listed above have total MOEs above 100, and therefore, do not exceed HED's level of concern. Exposures for four of the scenarios were estimated based on chemical-specific biomonitoring studies submitted by Dow AgroSciences (i.e., indoor crack and crevice treatment, broadcast turf application, and pre- and post-construction termiticide treatment) in which the PCOs wore label-specified personal protective equipment (PPE) or PPE in addition to that specified on the labels. Several of these studies did not represent the maximum label application rates, or only evaluated exposures for a few hours (i.e. 1-3 hours) of the work day, and consequently could underestimate exposures and risks to PCOs. Overall, the exposures and risks for LCOs/PCOs based on the chemical-specific biomonitoring studies are considered to be central tendency estimates because they evaluated less than a full day's exposure at the maximum label rate or they exclude accidental exposure (e.g., exposure resulting from a broken hose). In the absence of chemical-specific data, LCO/PCO exposures were estimated using data from PHED or the Draft Residential SOPs (12/18/97). The PHED data used for the mixer/loader for lawn treatment, and granular application (hand, belly grinder and push-type spreader) scenarios are representative of the chlorpyrifos uses as the surrogate data were monitored for similar scenarios. For example, granular bait was hand applied (with chemical-resistant gloves) to driveways and sidewalks; granulars were applied with a belly grinder to driveways and turf, and the push-type granular spreader was used on a lawn.

The results of the residential handler assessment for short- term exposure scenarios indicate that

all nine of the scenarios evaluated have total MOEs that exceed HED's level of concern defined by a target MOE of 1000. The residential handler MOEs ranged from 3 to 900 for dermal risk, from 120 to 57,000 for inhalation risk, and from 3 to 880 for total risk for the maximum, typical and even minimum label-recommended use rates. For a number of scenarios, multiple evaluations were conducted using application rates less than the maximum label rate, or application using different equipment or methods (i.e., ornamental treatment via low pressure hand wand and hose-end sprayer, and granular application via hand, belly grinder and push-type spreader) to provide information for risk mitigation and management decisions. MOEs for a few products evaluated at the minimum application use rate were greater than 1000 (i.e., crack and crevice spot treatment had a MOE of 1600), and therefore do not exceed HED's level of concern. Due to an absence of chemical-specific homeowner applicator studies, the majority of residential applicator exposures were estimated based on the data from the Draft Residential SOPs (December 1997) or updated assumptions for the SOPs to be released in 2000 (i.e., indoor crack and crevice treatment, broadcast turf application, granular formulation application, paintbrush application, and treatment of ornamentals). In all cases, it was assumed that residents wore short pants, short sleeves, and no gloves, in accordance with current Agency policy. Only one of the residential handler scenarios (outdoor ready to use product) was evaluated using chemical-specific data submitted by Dow AgroSciences. Dow AgroSciences has not submitted any other residential handler exposure data. The remaining scenarios were evaluated using the Residential SOPs or PHED.

Postapplication Residential/Worker Risks

The following scenarios result in MOEs less than 1000, or potential exposures that exceed HED's level of concern:

- Broadcast Turf Treatment Using a Liquid or Granular Formulation;
- Yard Sprays;
- Indoor Crack and Crevice Treatment;
- Pet Collar Products;
- Termiticide Treatments for Basement, Plenum, Slab and Crawlspace Construction Homes,
- Golf Course Use (adolescent and adult golfer) following treatment at the maximum rate of 4 lb ai/acre, and
- Perimeter treatments of Residences.

While the following scenarios result in MOEs greater than 100 or 1000 that do not exceed HED's level of concern for postapplication worker and residential exposures, respectively:

- Golf Course Use (adolescent and adult golfer) following treatment at the typical rate of 1 lb ai/acre;
- Aerial and ground-based fogger adult mosquitocide application, and
- Golf course mow/maintenance workers.

The results of the residential/worker postapplication exposure scenarios indicate that seven of the nine scenarios evaluated have MOEs that are less than 1000, and therefore exceed HED's level of concern. In addition, for post application exposure to children following perimeter applications to homes, it was estimated that more than seven hand-to-mouth events or more than 8 minutes of play on treated turf the day of treatment could result in potential exposures that could exceed the Agency's level of concern (i.e., MOE < 1000). MOEs that exceed HED's level of concern ranged from 6 to 980 for total risk. The only residential/recreational scenarios that resulted in MOEs above 1000 were adolescent and adult golfers for the typical application rate of 1 lb ai/acre (MOEs 1500-2400) and exposures from the aerial and ground-based fogger adult mosquitocide applications (MOEs are 15,000-43,000). In addition, the short-term MOEs for post application exposures for mow/maintenance workers at golf courses are above 100 (110 to 210) and therefore, do not exceed HED's level of concern, even at the maximum label rate of 4 lb ai/acre. Several of the residential postapplication exposures were estimated based on chemical-specific studies submitted by Dow AgroSciences (i.e., crack and crevice treatment of the kitchen and bathroom, broadcast treatment of turf with chlorpyrifos spray and granules, and termiticide treatment). The exposure and risk estimates based on the chemical-specific studies are considered to be reasonable estimates (i.e., arithmetic average, or median exposure was used to calculate risk). Because these studies were conducted in adults, conservative assumptions were used to estimate child exposures. However, because adult activity patterns differ from children, i.e., hand-to-mouth activity, some of the registrant-submitted chemical-specific studies could under-estimate a child's exposure (e.g., lawn studies are not designed to reflect any potential for incidental ingestion of residues from treated turf, soil and/or granules). In the absence of chemical-specific data, exposures were estimated based on data from the Draft Residential SOPs or updated assumptions from the SOPs to be released in 2000 (i.e., indoor crack and crevice treatment, and pet collar uses). Scientific literature studies, the AgDrift Model and the Draft Residential SOPs were used to evaluate adult mosquitocide uses.

No data are available to evaluate the postapplication residential exposures and risks associated with the use of insecticidal dust products indoors. In addition, there are no recommended procedures for evaluating these products in the Residential SOPs. Nevertheless, HED has concerns about the use of these products based on the low MOEs calculated using a study in the scientific literature (based on a carbaryl dust product that was used as a surrogate for chlorpyrifos) for residents or workers that could apply these products. HED recommends that the registrant provide additional information on the potential postapplication residential exposures associated with these products.

HED requests additional data for indoor crack, crevice and spot uses of chlorpyrifos. Specifically, HED requests treated room residue data for floors, furniture and other surfaces available for contact by children for both chlorpyrifos, and its primary degradation metabolite, 3,5,6-TCP following multiple treatments. Additionally, to chlorpyrifos air measurements are also required in treated rooms following multiple treatments (i.e., at a minimum 3 treatments 7 days apart). Residue data for 3,5,6-TCP are important due to the potential for accumulation and persistence of this environmental degradate.

HED requests confirmatory air monitoring data immediately following mosquito ground-based fogger or application due to potential concern for short-term inhalation exposures.

In addition, HED requests exposure and/or environmental data for all registered products and/or uses that are not assessed in this risk assessment.

2.0 BACKGROUND

Purpose

This document evaluates the potential health effects of occupational and residential exposure to chlorpyrifos, resulting from the residential uses of chlorpyrifos products. Exposures are evaluated for occupationally-exposed Pest Control Operators (PCOs), Lawn Care Operators (LCOs) residents who apply the chlorpyrifos products, and residential populations that may be exposed following pesticide application. This information will be incorporated into the Chlorpyrifos Reregistration Eligibility Decision Document (RED).

Criteria for Conducting Exposure Assessments

An occupational and residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure during use or to persons entering treated sites after application is complete. Both criteria are met for chlorpyrifos.

Summary of Toxicological Endpoints

The Hazard Identification Committee memos, dated June 2, 1999, March 4, 1999, and April 6, 2000 indicate that there are toxicological endpoints of concern for chlorpyrifos. The endpoints, and associated uncertainty factors used in assessing the risks for chlorpyrifos are presented in Table 1.

Table 1
Chlorpyrifos Hazard Endpoints, Uncertainty Factors and MOEs

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY	MOE for Workers	MOE for Residents
Acute Dietary (oral)	NOAEL=0.5 UF = 100 FQPA = 10 (infants, children and females 13-50)	plasma cholinesterase inhibition at peak time of inhibition (3-6 hours post exposure) at 1 mg/kg. Significant RBC ChE inhibition at 1.5 mg/kg/day	Blood Time Course Study (Mendrala and Brzak 1998) with support from Zheng et al. 2000	NR	1000 (infants, children and females 13-50)

Table 1 Chlorpyrifos Hazard Endpoints, Uncertainty Factors and MOEs					
EXPOSURE SCENARIO	**DOSE (mg/kg/day)**	**ENDPOINT**	**STUDY**	**MOE for Workers**	**MOE for Residents**
Short-Term (Dermal)	Administered Dermal NOAEL =5 Absorbed Dermal NOAEL = 0.15 (for biomonitoring) (a)	Plasma and RBC cholinesterase inhibition of 45 and 16%, respectively at 10 mg/kg/day following 4 days. (Dermal absorption factor not necessary for administered dermal NOAEL)	21-day dermal rat study	100	1000 (infants, children and females 13-50)
Intermediate- and Long-Term (Dermal)	Oral NOAEL =0.03	Plasma and RBC cholinesterase inhibition at 0.22-0.33 mg/kg/day. (Use 3% dermal absorption)	Weight of Evidence from 5 studies: 90 day and 2 year dog studies; 90 day and 2 year rat studies, and developmental neurotoxicity study	100	1000 (infants, children and females 13-50)
Short-,and Intermediate-Term (Inhalation)	Inhalation NOAEL= 0.1	Lack of effects in 2 rat inhalation studies at the highest dose tested. >40% plasma and >40% RBC cholinesterase inhibition following oral doses of 0.3 mg/kg/day (100% lung absorption assumed)	Two 90 day rat inhalation studies	100	1000 (infants, children and females 13-50)
Long-Term (Inhalation)	Oral NOAEL= 0.03	Plasma and RBC cholinesterase inhibition at 0.22-0.33 mg/kg/day (Assume inhalation and oral absorption equivalent)	Weight of Evidence from 5 studies: 90 day and 2 year dog studies; 90 day and 2 year rat studies, and developmental neurotoxicity study	100	1000 (infants, children and females 13-50)

NR = Not Relevant
UF = Uncertainty Factor
MOE = Margin of Exposure
RBC = Red blood cell
(a) Use absorbed dermal NOAEL of 0.15 mg/kg/day (5 mg/kg/day * 0.03 dermal absorption factor) for comparison with absorbed biomonitoring exposure.

As shown on Table 1, the short-term dermal NOAEL is 5 mg/kg/day from a 21-day dermal rat

study, based on plasma and red blood cell (RBC) cholinesterase (ChE) inhibition of 45% and 16%, respectively at 10 mg/kg/day. Therefore, no dermal absorption factor adjustment is necessary. For comparison with biomonitoring data that represents total absorbed dose, an adjusted dermal absorbed dose of 0.15 mg/kg/day (5 mg/kg/day * 0.03 dermal absorption factor) was used because for most scenarios, the majority of exposure results from dermal exposure (See HIARC report dated April 6, 2000, HED doc no. 014088 for detailed discussion). The intermediate- and long-term dermal NOAELs and long-term inhalation NOAEL are 0.03 mg/kg/day based on weight of the evidence for plasma and RBC ChE inhibition from five oral studies in dogs and rats. Because an oral NOAEL was selected, a dermal absorption factor of 3%, and a 100% default inhalation absorption factor (i.e., inhalation and oral absorption are equivalent) were used. Dermal absorption was estimated to be 3 percent based on the ratio of the oral lowest-observed-adverse effect level (LOAEL) of 0.3 mg/kg/day from the rat developmental neurotoxicity study (MRID Nos. 44556901, 44661001) to the dermal LOAEL of 10 mg/kg/day from the 21-day dermal study (MRID No. 40972801) for plasma and red blood cell cholinesterase inhibition. This absorption factor is comparable to the dermal absorption estimated from human data of 1-3% (MRID No. 00249203).

The short- and intermediate-term inhalation NOAEL is 0.1 mg/kg/day based on lack of effects in two rat inhalation studies at the highest dose tested. At higher oral doses of 0.3 mg/kg/day >40% plasma and >40% RBC ChE were observed in animals. The acute oral NOAEL is 0.5 mg/kg/day from an acute oral rat study that observed 28-40% plasma cholinesterase inhibition 3-6 hours after dosing male rats with a single dose of 1 mg/kg/day (HIARC memorandum from D. Smegal to S. Knizner, April 6, 2000, HED doc no. 014088). The acute oral NOAEL was used to assess short-term exposures resulting from incidental ingestion (i.e., hand to mouth exposure) of less than one week. This is considered appropriate because exposures and risks are calculated for the day of application, when residential exposures are expected to be greatest.

Summary of Use Pattern and Formulation

At this time some products containing chlorpyrifos are intended primarily for residential use, while some are intended primarily or solely for PCO/LCO use. Both occupational/PCO/LCO (non-agricultural) and residential use are evaluated in this document. Agricultural uses are addressed elsewhere.

Types of Pesticide/Targeted Pest/Use Sites

Chlorpyrifos is an organophosphate insecticide used extensively in residential settings by both residents and pest control operators (PCOs). Chlorpyrifos' most common trade names are Dursban, Empire 20, Equity, and Whitmire PT 270. Lorsban is a trade name for agricultural-use products. It is one of the top five insecticides used in residential settings. There are approximately 822 registered products containing chlorpyrifos on the market (REFs 9/14/99).

Approximately 20 to 24 million pounds are used annually in the U.S, with approximately 11 million pounds applied in non-agricultural settings (i.e., residences, schools, golf courses, parks). Registered uses include a wide variety of food, turf and ornamental plants, as well as indoor product uses, structural pest control, and in pet collars. It is used in residential and commercial buildings, schools, daycare centers, hotels, restaurants, hospitals, stores, warehouses, food manufacturing plants and vehicles. In addition, it is used as an adult mosquitocide. In 1998, Dow AgroSciences estimated that 70% of the urban chlorpryifos use involved termite control.

Formulation Types and Percent Active Ingredient

Chlorpyrifos, O,O-diethyl O-(3,5,6-trichloro-2-pyridyl) phosphorothioate, is an insecticide formulated as a wettable powder (containing 50% a.i.), emulsifiable concentrates (41.5-47%), dust (containing 0.1-7% a.i.), granular (containing 0.075%-2.5% a.i.), bait (containing 0.5% a.i.), flowables (containing 30% a.i.), impregnated material (containing 0.5-10% a.i.), pelleted/tableted (containing 0.5-1.0% a.i.), pressurized liquids (0.9-3.8% a.i.), and microencapsulated (0.5-20% a.i.). Dow AgroSciences states that formulations with concentrations greater than one pound a.i. per gallon (approximately 13% a.i.) are only for pest control on turf and ornamentals by professionals. Lower concentrations are available to homeowners from other suppliers for over-the-counter purchase. Except aerosols, granules and dusts, all formulated end-use products for application are diluted in water to a concentration of 1 percent a.i. or less (Dow AgroSciences 1998). However, HED is aware of at least one company that sells concentrated chlorpyrifos products (i.e., >13% up to 23% a.i.) to the public on the Internet (www.ADDR.com\~pestdepo\gizhome.html) as of March 1, 2000. According to DAS, wettable powders packaged in open bags and dry flowables are no longer available and are being removed from active registrations. They are not assessed in this chapter and are no longer eligible for re-registration. The Agency will work with DAS to delete any other formulations and/or products that are obsolete.

Method and Types of Equipment Used for Mixing/Loading/Applying

The Agency determines potential exposures to pesticides handlers by identifying exposure scenarios from the various application equipment-types that are plausible given the label uses. It is HED's responsibility to assess all uses that are allowable/plausible based on the label. Therefore, in all cases, the maximum labeled rates are assessed. If these maximum rates do not reflect actual practice, then those rates should be removed from the labels. DAS has attempted to provide the Agency with a survey on actual uses (i.e., MarQuest Survey) and the Agency has included this information to the extent possible. For example, the frequency that the maximum labeled rates are used may be important information to the risk manger during the Agency's risk mitigation phase.

- Handgun (LCO): Broadcast turf application
- Backpack/Low Pressure Handwand Equipment : crack and crevice treatment; spot treatment of turf; ornamental application

- Hose End Sprayer: Broadcast turf treatment, ornamental application
- Termite-injection equipment: subterranean termite control
- Belly-grinder equipment or a push type spreader: turfgrass
- Paintbrush: Treatment of infested wood

3.0 OCCUPATIONAL AND RESIDENTIAL EXPOSURE

3.1 Handler Exposures & Assumptions

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual residential use-patterns associated with chlorpyrifos. Based on the use patterns and potential exposures described above, 12 PCO/LCO/residential handler exposure scenarios were identified for chlorpyrifos. It was assumed that all residential handlers are female, and therefore the additional FQPA safety factor of 10 is applicable to this population.

Mixer/loader/applicator (M/L/A) exposure data for chlorpyrifos were required for a reregistration data call in (DCI) issued September 18, 1991 during the reregistration process, since one or more toxicological criteria had been triggered. Requirements for applicator exposure studies are addressed by OPPTS 875 Series Occupational and Residential Exposure Test Guidelines (February 10, 1998). Applicator exposure data were required previously by the Agency. The Pesticide Handlers Exposure Database (PHED), Version 1.1 was used for several scenarios. In addition, studies from the scientific literature were used for other situations.

The following studies monitoring PCO/LCO/residential application of chlorpyrifos were submitted by the registrant.

- MRID No./Accession No. 40026001. Vaccaro, J.R. (1986) Evaluation of Airborne and Whole Body Exposure of Lawn Care Specialists to Chlorpyrifos During Routine Treatment of Turf.

- MRID No. 44444801. Vaccaro, J.R. et al. (1997). Determination of Exposure and Dose of General Pest Control Operators to Chlorpyrifos during Routine Applications of Dursban Pro® Insecticide to Crack/Crevices and Spots. November 25, 1997. Laboratory Project Study ID: HEH 785.

- MRID No. 44729401. Barnekow, D.E, and Shurdut, B.A. (1998). Evaluation of Workers' Exposure to Chlorpyrifos During the Use of Dursban Pro® Insecticide Concentrate for Broadcast Turf Applications. November 10, 1998. Laboratory Project Study ID: HEA 97089.

- MRID No. 44739301. Barnekow, D.E, Cook, W.L., Meitl, T.J., and Shurdut, B.A. (1999). Exposure to Chlorpyrifos Whilt Applying a Ready to Use Formulation. January 14, 1999. Laboratory Project Study ID: HEA 97046.

- MRID No. 44729402. Barnekow, D.E, and Shurdut, B.A. (1998). Evaluation of

Workers' Exposures to Chlorpyrifos During the Use of Dursban® TC Termiticide Concentrate for Post-Construction Termiticide Applications. October 9, 1998 (original) and December 22, 1998 (amended). Laboratory Project Study ID: HEA 97054.

- MRID No. 44589001. Murphy, P.G., Beard, K.K., Chambers, D.M., Huff, D.W., Marino, T.A., Melichar, M., and Vaccaro, J.R. (1997). Evaluation of Workers' Exposures to Chlorpyrifos During the Use of Dursban® TC Termiticide Concentrate for Pre-Construction Termiticide Applications. December 15, 1997.

HED reviewed each of these studies and used the registrant-submitted data to estimate exposures to handlers/PCOs/LCOs applying chlorpyrifos-products in residential settings. A brief summary of each study is provided below, with reference to HED's memorandum that provides a more detailed review and analysis of the study. It should be noted that a number of the registrant-submitted studies conducted biomonitoring by measuring urinary concentrations of the primary chlorpyrifos metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP), to estimate chlorpyrifos exposures. Prior to the studies, baseline urinary 3,5,6-TCP concentrations were determined in the study volunteers, and these baseline measurements were subtracted from the exposure-related 3,5,6-TCP concentrations measured in the biomonitoring study. It is important to note that most individuals in the U.S., and nearly all the subjects in the Dow AgroSciences biomonitoring studies had low levels of urinary 3,5,6-TCP prior to study commencement, indicating a baseline exposure to chlorpyrifos, chlorpyrifos methyl or their metabolite/degradate 3,5,6-TCP.

In the absence of chemical-specific monitoring data, data obtained from PHED Version 1.1 were used to assess handler exposures. PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts--a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenario (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal or lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central

tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of the data quality is based on a number of observations and the available quality control data. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments. This surrogate exposure guide serves as the basis for this assessment. Best available grades are assigned to the unit exposures as follows: matrices with grades A and B data <u>and</u> a minimum of 15 replicates; if not available, then grades A, B and C data <u>and</u> a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High	=	grades A and B and 15 or more replicates per body part;
Medium	=	grades A, B, and C and 15 or more replicates per body part; and
Low	=	grades A, B,C, D and E <u>or</u> any combination of grades with less than 15 replicates.

There are three basic risk mitigation approaches considered appropriate for controlling occupational exposures. These include the use of engineering controls, administrative controls, and the use of personal protective equipment (PPE). Engineering controls are recommended for occupational hazards wherever feasible, because they have the least continual human implementation or intervention necessary in achieving decreased exposure levels. Occupational handler exposure assessments are typically completed by HED using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an appropriate margin of exposure. The baseline clothing ensemble for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, no chemical-resistant gloves (there are exceptions pertaining to the use of chemically-resistant gloves, footwear and aprons and these are noted), and no respirator. The first level of mitigation generally applied is PPE. As reflected in the calculations that follow, PPE may involve the use of an additional layer of clothing, chemical-resistant gloves, and/or a respirator. The next level of mitigation considered in assessing exposure and risk is the use of appropriate engineering controls which, by design, attempt to reduce or eliminate the potential exposure. Examples of commonly used engineering controls include enclosed tractor cabs, closed mixing/loading/transfer systems, and water-soluble packets. [Note: Administrative controls may include methods such as lowering application rates for handler exposure scenarios.]

For chlorpyrifos, a typical baseline scenario was not evaluated for PCOs/LCOs because it was assumed they would, at a minimum, require the label-specified PPE, in accordance with current

label requirements.

Occupational/Residential Handler Exposure/Risk Assessment

The following 12 PCO/LCO/residential application scenarios were considered:

(1) Indoor Crack and Crevice or Spot Application

Commercial Applicator (MRID No. 44444801)

The registrant submitted a passive dosimetry study that characterizes exposures to professional pest control operators (PCO) during application of 0.29% Dursban Pro® (EPA Reg No. 62719-166) on cracks, crevices, and spot treatment of residential and commercial buildings. The equipment used for spraying the product was a 2-gallon, hand pressurized B&G sprayer. A total of ten professional male PCOs from three state-wide and local pest control companies were evaluated. Five of the ten volunteers performed a second replicate for a total of fifteen replicates. Each volunteer was dressed in long cotton underwear, a cotton overall with long sleeves and long pant legs, cotton socks, chemically-resistant shoes and protective gloves during the mixing process. Eye protection was used by the PCOs when chlorpyrifos was sprayed overhead. HED evaluated this study in DP Barcode 241777 and D241838 (Memorandum from D. Smegal to M. Hartman, April 19, 1999).

Dermal exposure was quantified using passive dosimetry (long cotton underwear, cotton coveralls with long sleeves and long pant legs, and cotton socks; hand washes; and head patches). Inhalation exposure was measured using a personal air pump attached to the test subject's belt. The pump was connected with a cassette containing a polyvinyl chloride filter and a cellulose support pad (37-mm diameter, 0.8-µm pore size) followed by a Chromosorb 102 vapor collection tube to evaluate inhalation exposures in the breathing zone of workers.

The amount of active ingredient (ai) handled per replicate ranged from 0.09 g to 31.04 g (mean = 9.20 g; S.D. = 9.77 g). The volume applied per replicate ranged from 0.02 gallons to 2.8 gallons (mean = 0.84 gal.; S.D. = 0.81 gal.). The sampling time per replicate ranged from 248 to 591 minutes (mean = 378 minutes). Of the sampling time, 2.3 percent (12 minutes) to 43 percent (154 minutes) was used for actual spraying activities (mean = 21 percent, or 76 minutes).

The data were used to estimate dermal and inhalation unit exposures (μg/ lb ai) based on the worker-specific amount handled (lb ai) per day, and the worker-specific total dermal or inhalation exposure based on the dosimetry measurements. The mean absorbed dermal (adjusted for 3% dermal absorption) and inhalation unit exposures of 1790 and 532 μg/lb ai, respectively were then used to calculate the total dermal and inhalation doses for three scenarios (average, minimum and maximum) based on the range of chlorpyrifos (lb ai) handled by the PCOs during the 15 replicates. The amount (lb ai) handled per worker varied significantly and ranged from 0.0002 to 0.0684 lb ai, with a mean of 0.02 lb ai. All exposures were normalized to a 70 kg body weight in accordance with HED policy for passive dosimetry measurements.

A summary of the dermal and inhalation dose estimates are presented on Table 2. The dermal dose estimates were already adjusted for 3% dermal absorption. Because dermal and inhalation unit exposure data sets are lognormally distributed, the current HED policy is to use the geometric mean for assessing exposure. As shown on Table 2, the total dermal absorbed dose ranges from 0.005 to 1.75 μg/kg/day, with a geometric mean of 0.51 μg/kg/day. The dose estimates resulting from inhalation range from 0.0015 to 0.52 μg/kg/day, with a geometric mean of 0.15 μg/kg/day. This study demonstrates that on average 71% of the total exposure (i.e., absorbed dose) to PCOs during crack and crevice treatment results from dermal exposure, while inhalation exposure contributes on average approximately 29% of the total dose. The dose estimates from this study were used to assess long-term exposures to a PCO.

The exposure data partially meet the criteria specified in Subdivision U (currently referred to as Series 875 Group A). There is a large variation in the results, due primarily to the large range of chlorpyrifos ai handled (0.09 to 31.04 g), volume applied per replicate (0.02 to 2.8 gallons), sampling time (248 to 591 minutes or 4 to 9.85 hours), spray time (12 to 154 min) and percent chlorpyrifos handled (0.05 to 0.53%). In fact, only two of the fifteen replicates reflect the maximum recommended label concentration of 0.5% chlorpyrifos; an average of 0.29% chlorpyrifos was handled by the fifteen PCOs. In addition, it is possible that different tasks/activities associated with pesticide application in residential and commercial locations contributed to the range of exposures. However, the impact of applicator activities can not be determined due to an absence of study details. Despite the limitations, the data collected in this study are of sufficient scientific quality to be used in the RED document.

Residential Application

In the absence of chemical-specific data, short-term doses to residents that could treat their homes with a crack and crevice product in an aerosol can were evaluated using data from PHED V1.1, and the Residential SOPs (12/18/97). It was assumed that a residential applicator would wear short-sleeves, short pants and no gloves, that an average applicator weighs 70 kg, and applies the entire contents of a 16 ounce aerosol can that contains 1% ai chlorpyrifos (w/w, 0.16 oz or 4.5 g) (EPA Reg. 026693-00003) as a high end estimate for a heavy infestation, and the application of a 16 oz can of a 0.5% ai chlorpyrifos (EPA Reg 239-2619) to represent a lesser concentration. In addition, an assessment was conducted for a spot treatment, where a homeowner could apply 2 oz of a 0.5% ai product. The estimated doses are presented in Table 2. There is medium confidence in the dermal and inhalation unit exposure estimates from PHED, which are based on 30 dermal replicates of ABC grades, 15 hand replicates of grade A, and 30 inhalation replicates of grade ABC. The representativeness of the PHED data are excellent, as the surrogate study monitored exposures resulting from an insecticide aerosol can while treating baseboards in a kitchen.

(2) Broadcast Turf Application (MRID No. 44729401

LCO Applicator Exposures

Exposure estimates were derived from a chemical-specific Dow AgroSciences study in which workers were monitored during commercial lawn care application. HED evaluated this study in

DP Barcode D252357 (Memorandum from D. Smegal to M. Hartman, April 15, 1999). This study characterizes exposures to lawn care operators (LCOs) that apply an average of 183 gallons of 0.12 percent diluted Dursban Pro (EPA Reg No. 62719-166) at a nominal rate of 1 lb ai/acre by broadcast applications to turf for an average of 6 hours (range of 4.4-8.2 hours). The actual spray time ranges from 66 to 171 minutes (average 1.5 hours). Exposures were estimated based on both dosimetry measurements and biomonitoring of urinary 3,5,6-TCP (the primary metabolite of chlorpyrifos). The study examined exposures to 15 lawn care insecticide applicators from two different companies in Ohio, that each treated 11-15 turf blocks (one block equals approximately 6,500 ft^2). The total area of treated turf ranged from 74,740 to 97,500 square feet (mean of 95,983 ft^2 or approximately 2.2 acres), while the total amount of chlorpyrifos handled ranged from 1.57 to 2.95 lb ai chlorpyrifos (mean of 2.17 lb ai). In addition, the workers unloaded and reloaded the hose following application to each lawn (i.e., repeated 15 times per replicate). This study does not characterize exposures associated with mixing and loading the insecticide. It was assumed that lawn care professionals could treat lawns for both intermediate and long term durations.

Each LCO wore pre-laundered cotton coveralls, a pre-laundered cotton socks, cotton briefs, and cotton T-shirts (undergarment); and a hat with affixed denim patches. At the end of the application, these dosimeters were collected from each applicator. The coverall and undergarments were sectioned into pieces representing arm, leg, and torso regions. Patches were affixed to the hat to serve as a surrogate for face, head and neck exposure. In addition, each LCO wore chemically-resistant nitrile gloves and knee high chemically-resistant boots (note that knee-high boots are not required by the label). Inhalation exposure was assessed through the use of personal air sampling pumps.

The total absorbed doses estimated from dosimetry range from 0.21 to 2.24 µg/kg/day, with a mean of 0.88±0.62 µg/kg/day. Approximately 33 percent of the absorbed doses resulted from inhalation and 67 percent from dermal exposure. The total absorbed dose estimated from biomonitoring ranged from 0 to 4.84 µg/kg/day, with an arithmetic mean of 0.65 ± 1.43 µg/kg/day (this average includes seven of the 15 workers that had exposures of zero because the exposure contribution from the application could not be distinguished from the high baseline chlorpyrifos exposure based on pre-study urinary 3,5,6-TCP concentrations). The geometric mean dose for workers who had exposure above baseline levels (n=8) is 0.4 µg/kg/day. In accordance with HED policy, the geometric mean is used to assess exposures because the biomonitoring data are lognormally distributed. The mean values are in somewhat good agreement with the estimates from dosimetry. The biomonitoring arithmetic average for the eight workers who had exposures above baseline was 1.23 µg/kg/day (i.e., excludes the seven workers with no exposure from lawn treatment). The registrant speculated that the highest exposure of 4.84 µg/kg (for OH05) was from a secondary source because 67% of the 3,5,6-TCP was excreted on day 5 post exposure. However, this value was included in the average dose because each volunteer was instructed to avoid chlorpyrifos for 10 days prior and 5 days following the study.

Pre-exposure baseline chlorpyrifos doses ranged from 0.2 to 3.73 µg/kg with a mean of 1.54 µg/kg, despite the fact that workers were instructed to avoid chlorpyrifos exposure 10 days prior to the study initiation. The high baseline chlorpyrifos dose makes it difficult to interpret the biomonitoring results. For example, seven of the fifteen workers had exposure levels (based on

urinary 3,5,6-TCP) less than baseline levels, and therefore, their exposure from broadcast turf application is probably within the seven worker-specific baseline range (0.94 to 3.73 μg/kg), and not zero as concluded by the registrant.

The analysis of blood samples drawn from each applicator 24 and 48 hours post exposure indicated that no significant depression in plasma and red blood cell cholinesterase activity, relative to pre-study activity levels, occurred to the applicators after the application of the Dursban Pro insecticide. All of the plasma and red blood cell cholinesterase activities were within the reference range for the laboratory of 1,000 to 3,500 and 5,300 to 10,000 international units (IU)/ liter (L), respectively except for the plasma pre-exposure level for volunteer OH15 (352 IU/L). It should be noted, however, that in animals peak cholinesterase inhibition occurs 3-6 hours post exposure. In addition, the prior exposure of many of these PCOs may have resulted in suppressed baseline cholinesterase levels.

The lower leg (calves) coverall samples contained approximately 80% of the total coverall chlorpyrifos, despite that only 9% of the dermal dose was attributed to the sock dosimeters. However, it should be noted that each worker wore knee high chemical resistant footwear during application (only chemical resistant footware is required by the label, not knee high footwear). In addition, the exposure from hand washes represented 11% of the total dermal exposure, despite the fact that each worker wore chemically-resistant gloves.

The majority of the exposure data meet the criteria specified in Series 875 Group A. The applications of 1 lb ai/acre used in this study represented 25% of the maximum rate for treatment of subsurface feeding insects of 4 lb ai/acre. For example, the study applied 2 gallons diluted spray/1000 ft^2 or a nominal rate of 1 lb ai/acre , while the label allows up to 4 lb ai/acre [2 lb ai/gallon at 2 gallon/acre (8 qts product/acre) for white grubs]. Therefore, it is possible that this study underestimates the actual exposures to LCOs that apply the maximum label rate for subsurface soil broadcast treatment. For comparison purposes, dose estimates were also calculated based on the maximum label rate of 4 lb ai/acre, as shown on Table 2. The label maximum adjusted dose estimates are four times higher than the estimated biomonitoring exposures, with a geometric mean of 1.6 μg/kg/day assuming there is a direct correlation between application rate and exposure.

In addition, TruGreen/ChemLawn (1999) data for 193 workers indicate that the actual spray time LCOs is 2.75 hours with a total work shift work time of 8.48 hours, in contrast to the 1.5 hour spray time and 6 hour work day evaluated in this biomonitoring study. Consequently, the LCO exposure estimates are likely to be underestimated, based on real life work conditions.

LCO Mixer/Loader Exposures

Because the biomonitoring study did not evaluate exposures for mixer and loading activities, these scenarios were evaluated using PHED V1.1. Two unit exposures for a mixer/loader handling liquid were evaluated and are presented in Table 2. One for a single layer of clothing and gloves, and the second for two layers of clothing and gloves. There is high confidence in the data quality for the dermal and inhalation unit exposure estimates from PHED.

Residential Application

HED has no data monitoring chlorpyrifos exposures to residents during broadcast or spot treatment of turf. Therefore, exposures were evaluated based on data obtained from the Residential SOPs (also from PHED V1.1) for mixing/loading and application activities. This assessment evaluates both the broadcast and spot treatment of turf, which are assumed to be short-term scenarios for residents. For the broadcast treatment, it was assumed that a resident would use a hose end sprayer to treat 0.5 acre/day of turf, which represents the mean to upper-percentile range of the distribution of lawn size, with Dursban 1-12 Insecticide (EPA Reg No. 62719-56; 12.6% ai; 1 lb ai/gallon). For spot treatment of turf, it was assumed that a resident would use a low pressure handwand to treat 1000 ft^2 with the same chlorpryifos product. Recent lawn size survey data suggest that 0.5 acre lawn size represents 73% of 2300 respondents, while nearly 16% of the respondents had lawn sizes that ranged from 0.57 to 1 acre (Outdoor Residential Use and Usage Survey and National Gardening Association Survey 1999). It is possible that this survey included residents that do not have yards (i.e., condominium, apartments, urban dwellings, etc). The dose estimates for residential use assume that individuals wear short pants, short sleeves and no gloves. For the hose-end sprayer, there is low confidence in dermal and inhalation unit exposure estimates, which are based on 8 dermal and inhalation replicates of C grade data, and 8 grade E hand replicates. For the low pressure handwand (liquid/open pour), there is low confidence in dermal unit exposure estimates, which are based on 9-80 dermal replicates of ABC grade data, and 70 hand replicates of all grades. There is medium confidence in the inhalation unit exposure estimates, which are based on 80 inhalation replicates of ABC grade data. The label recommends diluting 3-12 oz of Dursban 1-12 Insecticide (12.6% ai; 1 lb ai/gallon) with 1 to 3 gallons of water. As shown on Table 2, a range of dose estimates were calculated for broadcast treatment, assuming application of 22 gallons of diluted product (i.e., 1 gallon/1000 ft^2 or 22 gallons per 0.5 acre) at both the minimum and maximum dilution rates of 3 to12 oz/gallon/ water/ 1000 ft^2. The short-term dermal doses (not adjusted for absorption) range from 214 to 857 μg/kg, while the inhalation exposures range from 0.07 to 0.27 μg/kg/day. For spot treatment, it was assumed a resident could apply 1 gallon diluted product at the maximum application rate of 12 oz ai/gallon water 1000 ft^2, which resulted in short-term dermal and inhalation doses of 134 and 0.04 μg/kg/day, respectively. In addition, application of 1 gallon at the minimum application rate of 3 oz ai/gallon water 1000 ft^2 resulted in short-term dermal and inhalation doses of 34 and 0.01 μg/kg/day, respectively. These short-term dermal and inhalation dose estimates are presented on Table 2.

(3) Golf Course Use

Chlorpyrifos is applied to golf course turf. No chemical-specific data were submitted by DAS to assess the application of chlorpyrifos to golf courses by workers. According to the National Golf Course Superintendents Association (personal communication with Mark Hartman, SRRD) the wettable powder formulation is by far the most used formulation and that granular are not used often, if at all. The Association has mailed out a survey to their membership on use patterns (size of treated areas, number of applications, etc.) which they expect to complete shortly. In the interim, an assessment is provided for both the 1 and 4 lb ai/acre rates for both the liquids and wettable powders. Exposures were assessed for workers that mix/load and apply chlorpyrifos to golf course turf. Exposures were based on PHED VI.1 data, and were assumed to be short-term (i.e., less than 30 days) for contact with chlorpyrifos residues the day of treatment. The dose estimates are presented on Table 2. The following assumptions were used in this assessment:

- Application rates: Dursban Turf Insecticide (EPA Reg. No. 62719-35) turf rates range from 1 lb ai/acre for ants, cutworms, sod webworm, etc. to 4 lb ai/acre for white grubs (specific directions to water in using ½ to 1 inch of water) and bluegrass billbugs.

- Broadcast application of chlorpyrifos to non tee and green areas is assumed to be applied using groundboom equipment. Applications to greens and tees are assumed to be applied by handheld equipment.

In addition to the PHED data, HED also evaluated chlorpyrifos exposures during groundboom application based on biomonitoring data obtained from MRID 42974501. This study assessed workers in an open cab, wearing coveralls over a T-shirt, and no gloves. These results are also presented on Table 2.

(4) Application of a Ready-To-Use Formulated Product (MRID No. 44739301)

Exposure estimates were derived from a chemical-specific registrant-submitted study in which 15 homeowners were monitored during the outdoor application of a ready-to-use formulated product, Ortho Ant Stop containing approximately 0.5% chlorpyrifos. HED evaluated this study in DP Barcode D252738 (Memorandum from D. Smegal to M. Hartman, April 29, 1999). In this study, homeowners applied up to five 24 oz. ready-to-use disposable bottles (with screw on tops) over a one hour duration to the outside foundation and perimeter of the house, and other areas (e.g., flower beds) where ants were present. A total of fifteen adult volunteers (nine females and six males) in the area of Indianapolis, Indiana were evaluated. The volunteers wore standard clothing that consisted of a short-sleeve coveralls with long pants, underwear, and a baseball style hat, but no gloves. Volunteers wore their own uncontaminated shoes. Each volunteer was instructed not to treat their homes or yards with chlorpyrifos containing products either immediately before, during or after the conduct of the study, and to avoid chlorpyrifos-containing products 10 days prior and 4 days after application. The amount of active ingredient (ai) handled per replicate ranged from 0.015 g to 0.038 g (mean = 0.033 g; S.D. = 0.006 g).

Exposures were estimated based on both dosimetry measurements and biomonitoring of urinary 3,5,6-TCP. Dermal exposure was quantified using passive dosimetry [cotton underwear (T-shirt, briefs or women's underwear), short-sleeve cotton coveralls with long pant legs, and hand washes; and a baseball style hat]. Inhalation exposure was measured using a personal air pump attached to the test subject's belt. The pump was connected by tygon tubing with a 37-mm mixed cellulose ester filter (0.8-μm pore size) connected to a Chromosorb 102 vapor collection tube to evaluate inhalation exposures in the breathing zone of volunteers.

The total absorbed dose estimated from passive dosimetry range from 0.03 to 0.86 μg/kg/day, with a mean of 0.25±0.25 μg/kg/day. Approximately 12 percent of the absorbed dose, as estimated from the passive dosimetry data, resulted from inhalation (mean 0.03 μg/kg/day) and 88 percent from dermal exposure (0.23 μg/kg/day). The total absorbed dose estimated from biomonitoring ranged from 0 to 1.9 μg/kg/day, with an arithmetic mean of 0.49 ± 0.59 μg/kg/day, and a geometric mean of 0.24 μg/kg/day. The mean values are in somewhat good agreement with the estimates from dosimetry. The biomonitoring results are slightly higher, but given that hand wash residues contribute on average 57% of the total dermal exposure, it is possible that the volunteers may have incidentally ingested chlorpyrifos as well (which would

only be captured in the biomonitoring results). Baseline chlorpyrifos pre-exposure ranged from 0.05 to 0.3 µg/kg with a mean of 0.12 µg/kg, despite the fact that volunteers were instructed to avoid chlorpyrifos exposure 10 days prior to the study initiation.

The geometric mean biomonitoring dose estimate of 0.24 µg/kg/day is used in this risk assessment in accordance with HED policy for lognormally distributed data sets. This dose was directly used to assess risk based on a comparison with the dermal absorbed NOAEL of 150 µg/kg/day from the 21 day dermal rat study (5000 µg/kg/day * 0.03 dermal absorption factor), because most of the exposure is via the dermal route. This dose estimate was divided into dermal and inhalation doses based on the passive dosimetry results, (i.e., 88% dermal and 12% inhalation), because there are different short-term inhalation and dermal endpoints for risk assessment. The resulting absorbed dose estimates used in the risk assessment are 0.029 µg/kg/day for inhalation and 0.21 µg/kg/day for dermal, as shown on Table 2. For short-term scenarios (such as residents), the absorbed dermal dose estimate from the biomonitoring results (absorbed dose) was further adjusted to an estimated dermal non-absorbed dose of 7 µg/kg/day (using a 3% dermal absorption factor) for direct comparison with the short-term dermal toxicity endpoint. These dose estimates represent a central-tendency to high-end scenario for residential applicators, who are more likely to apply one bottle of product rather than the five bottles used in the study, but could wear shorts rather than long pants. Chlorpyrifos residues on pants were on average 70% of the total dermal exposure.

This study met most of the requirements contained in the Series 875 Group A, Applicator Exposure Monitoring Test Guidelines, and the data are useful for risk assessment.

(5) Insecticidal Dust Product Application (Bulbous Duster or Shaker Can)

HED has no data monitoring exposures from chlorpyrifos application using a duster. Therefore, chlorpyrifos exposures were evaluated using a study in the scientific literature in which a dust formulation was applied to a home garden (Kurtz and Bode 1985). This analysis is presented in a memo from D. Jaquith to Chlorpyrifos file, June 11, 1996 entitled Documentation of Applicator Exposure Assessment for Chlorpyrifos Reregistration Eligibility Document--Application in the Residential Environment. Although chlorpyrifos dust products are not registered for garden use, this study is considered to represent the best surrogate data available because it measures exposure per quantity of product handled. For this assessment, both a residential applicator and utility workers (i.e., during application of product to underground wires or cables) were evaluated. It was assumed that a homeowner could dispense a 10 oz can of a 1% ai product (2.83 g ai) (EPA 62719-54) to treat a heavily infested home, while it was assumed a worker could handle a more concentrated product (Rainbow Ko Fire Ant Killer, 7% ai, EPA Reg 13283-17), which is sold in both 4 oz and 100 oz containers (7.9 and 198.4 g ai, respectively). The label notes that the 4 oz container treats 1 sq ft^2, while the 100 oz container treats up to 100 ft^2. It was assumed that a residential applicator would be exposed short-term (i.e., 1-30 days), and that a worker could be exposed both short- and intermediate-term (i.e., 30 days to several months).

In the study, 24, 15-minute replicates were available for individuals that dispensed 190 to 220 g of a 5 percent carbaryl dust product (9.5-11 g ai or 0.021-0.024 lb ai) using a shaker can to corn and beans. Measurements were taken of the total deposition of the material on the skin/clothing

surfaces. The product was applied for 15 minutes, enough time to treat an average home garden or a heavily infested home. The total potential dermal exposure, measured using total deposition was 11 mg per 15 minute treatment (5.0×10^3 mg/lb ai). Respiratory exposure was not measured.

There are no data adequate to determine the amount of protection that clothing offers to dust formulations. Therefore, HED assumed that areas covered by clothing offer 50 percent protection and that gloves offer 90 percent protection. HED estimated exposure for workers based on total deposition, wearing long pants, long sleeves, and gloves to be 4.5 mg per 15 minutes (or 4.5 mg/10 g ai carbaryl) and total deposition for residents wearing long pants, short sleeves with no gloves to be 4.9 mg per 15 minutes (or 4.9 mg/10 g ai carbaryl). These data were normalized to g ai chlorpyrifos handled to assess an in home dust treatment. Therefore, residential chlorpyrifos exposure was estimated to be 1.4 mg ai (i.e., 4.9 mg/10 g ai carbaryl * 2.83 g ai chlorpyrifos), while worker exposure was estimated to range from 3.6 to 89 mg ai chlorpyrifos for a 4 oz and 100 oz container, respectively (i.e., 4.5 mg/10 g ai carbaryl * 7.91 or 198.4 g ai chlorpyrifos). As shown on Table 2, the resulting short-term dermal dose for residents is 20 μg/kg/day, while the short- and intermediate- term dermal doses to workers range from 51 to 1275 μg/kg/day. These exposure estimates are considered to be conservative because the quantity of chlorpyrifos dust used indoors by residents is likely to be much less than the quantity of dust products typically used in gardens.

(6) Granular Formulation Application by Hand

HED has no data monitoring exposures from chlorpyrifos application of granular formulation by hand (EPA Reg. 62715-14, 62715-210). Therefore, exposures were evaluated based on data obtained from PHED V1.1. for LCOs, and the Residential SOPs for residential applicators (also from PHED V1.1). The unit exposure estimates for LCOs assume workers wear chemical-resistant gloves plus long-sleeve shirt and long pants. There is medium confidence in the dermal and inhalation unit exposure estimates, which are based on 16 dermal, 15 hand, and 16 inhalation replicates of ABC grade data. It should be noted that the PHED unit exposure estimates are based on a single study in which a test subject wearing chemical-resistant gloves spread the granular formulation around the outside of the residence and over 90 percent of the samples contained no detectable material. Therefore, the exposure estimate is driven by the limit of detection of the analytical method. Because of the non-detection issue, HED also evaluated a resident wearing long pants, long sleeved shirt and gloves. In addition, dose estimates were calculated assuming LCOs wear a double layer of clothing. The dose estimates for residential use assume that individuals wear short pants, short sleeves and no gloves. In addition, residents that wear long pants, long sleeves and gloves were also evaluated due to the large number of non-detectable residues in the study. There is also medium confidence in the unit exposure estimates for residential exposure, which are based on 16 dermal, hand and inhalation replicates each of ABC grade data. It was assumed that an average application dispensed is 0.0459 lbs of active ingredient, which assumes a LCO or resident treats 1000 ft^2 of turf with an active granular formulation at 2 lb ai/acre. A preliminary review of a recent registrant-submission suggests that this rate is the typical, median rate used by the LCO industry to treat subsurface soil feeding insects (Jefferson Davis Associates, Inc. 1999). It was assumed that a LCO could apply a granular formulation for durations greater than 30 days and up to several months (i.e., intermediate term), while a resident is more likely to apply a granular formulation once or twice

a season (i.e., short-term). Data submitted by TruGreen/ChemLawn (1999) shows that LCOs apply chlorpyrifos-containing insecticides April through October (approximately 6 months).

(7) Loading Granular Formulation and Applying with Belly-Grinder Equipment

HED has no data monitoring exposures from chlorpyrifos application of granular formulation using a belly-grinder. Therefore, exposures were evaluated based on data obtained from PHED V1.1. for LCOs, and the Residential SOPs for residential applicators (also from PHED V1.1). The unit exposure estimates for LCOs assume workers wear chemical-resistant gloves plus long-sleeve shirt and long pants. There is low confidence in the dermal unit exposure estimates, which are based on 29 to 45 dermal replicates of ABC grade, and 20 hand replicates of all grades of data. There is high confidence in the inhalation unit exposure estimates which are based on 40 replicates of AB grade data. In addition, dose estimates were calculated assuming LCOs wear a double layer of clothing. The unit exposure estimates for residential use assume that individuals wear short pants, short sleeves and no gloves. There is also medium confidence in the dermal unit exposure estimates for residential exposure, which are based on 20 to 45 dermal, and 23 hand replicates each of ABC grade data. There is high confidence in the inhalation unit exposures, which are based on 40 replicates of AB grade data. Similar to the scenario discussed above, it was assumed that an average application dispensed is 0.97 lbs of active ingredient based on a DAS-submitted study of a granular formulated product (MRID 44167101). This assumption is based on a LCO or resident that treats 0.5 acre of turf with an active granular formulation at 2 lb ai/acre. Recent lawn size survey data suggest that 0.5 acre lawn size represents 73% of 2300 respondents., while nearly 16% of the respondents had lawn sizes that ranged from 0.57 to 1 acre (Outdoor Residential Use and Usage Survey and National Gardening Association Survey 1999). It is possible that this survey included residents that do not have yards (i.e., condominium, apartments, urban dwellings, etc). A preliminary review of a recent registrant-submission suggests that this rate is the typical, median rate used by the LCO industry to treat subsurface soil feeding insects (Jefferson Davis Associates, Inc. 1999). HED also evaluated a spot treatment scenario of 0.0459 lb ai per 1000 ft^2. It was assumed that a LCO could apply a granular formulation for durations greater than 30 days up to several months (i.e., intermediate term), while a resident is more likely to apply a granular formulation once or twice a season (i.e., short-term). Data submitted by TruGreen/ChemLawn (1999) shows that LCOs apply chlorpyrifos-containing insecticides April through October (approximately 6 months).

(8) Loading Granular Formulation and Applying with a Push-Type Spreader

HED has no data monitoring exposures from chlorpyrifos application of granular formulation using a push-type spreader. Therefore, exposures were evaluated based on data obtained from PHED V1.1. for LCOs, and the Residential SOPs for residential applicators (also from PHED V1.1). The unit exposure estimates for LCOs assume workers wear chemical-resistant gloves plus long-sleeve shirt and long pants, while residents are assumed to wear short pants, short sleeves and no gloves. There is low confidence in the dermal unit exposure estimates for LCOs and residential applicators due to inadequate replicate numbers, which are based on 0 to 15 dermal replicates of C grade data, 0 hand replicates for LCOs and 15 hand replicates each of C grade data for residents. There are no head, neck or hand replicates for the LCO clothing scenario. In addition, dose estimates were calculated assuming LCOs wear a double layer of clothing. For residents, a 50 percent protection factor was used to back calculate a short-sleeved

scenario from the long sleeved data. There is high confidence in the inhalation unit exposure estimates for both LCOs and residents, which are based on 15 replicates of B grade data. Similar to scenario discussed above, it was assumed that an average application dispensed is 0.97 lbs of active ingredient based on a DAS-submitted study of a granular formulated product (MRID 44167101). As noted above, this assumption is based on a LCO or resident that treats 0.5 acre of turf with an active granular formulation at 2 lb ai/acre. Recent lawn size survey data suggest that 0.5 acre lawn size represents 73% of 2300 respondents., while nearly 16% of the respondents had lawn sizes that ranged from 0.57 to 1 acre (Outdoor Residential Use and Usage Survey and National Gardening Association Survey 1999). It is possible that this survey included residents that do not have yards (i.e., condominium, apartments, urban dwellings, etc). A preliminary review of a recent registrant-submission suggests that this rate is the typical, median rate used by the LCO industry to treat subsurface soil feeding insects (Jefferson Davis Associates, Inc. 1999). It was assumed that a LCO could apply a granular formulation for durations greater than 30 days up to several months (i.e., intermediate term), while a resident is more likely to apply a granular formulation once or twice a season (i.e., short-term). Data submitted by TruGreen/ChemLawn (1999) shows that LCOs apply chlorpyrifos-containing insecticides April through October (approximately 6 months).

(9) Pre-Construction Termiticide Use for Subterranean Termite Control (Mixing/Loading and Applying) (MRID No. 44589001)

Exposure estimates were derived from a chemical-specific study submitted by Dow AgroSciences in which workers were monitored during application of chlorpyrifos, as the termiticide Dursban® TC (43.2% ai) (EPA Reg. 62719-47), during pre-construction termiticide treatments. HED evaluated this study in DP Barcode D247635 (Memorandum from J. Cruz to M. Hartman, May 24, 1999). This study quantified exposures to a mixer/loader/applicator (M/L/A) during mixing/loading/application and tarp pulling processes.

The M/L/A performed an open-pour mixing/loading task in which a PCO loaded Dursban® TC concentrate into a mixing tank containing the appropriate amount of water. After mixing, the diluted product was sprayed onto the soil using a hand-held sprayer and then two workers (tarp pullers) laid the untreated plastic tarp over the treated soil prior to pouring the concrete foundation.

The product was diluted to a nominal rate of 1% (actual 1.44%) prior to application. All applications were made with a low pressure spray equipment fitted with a hand-held hose-end sprayer or spray wand fitted with a shrouded rose nozzle. The flow rates at which the spray was applied to the sites varied depending on the truck, but in general applications were between 8 to 12 gallons/minute. There were 17 M/L/A replicates, representing at least three hours exposure time per replicate. There were16 tarp puller replicates each representing 6-7 minutes. Each worker completed 8 tarp pulling replicates in less than one hour. M/L/A wore long underwear, a long sleeved shirt, long pants, and PPE consisting of rubber boots, tyvek or cotton coveralls, and arm-length gloves (note the label only requires a single layer of clothes; the coveralls and arm-length gloves are not required). Each worker removed their PPE after the spray operation was concluded. The tarp pullers wore a long sleeved shirt, long pants socks, leather and/or rubber boots, and a hat. In addition, one half (8) of the workers wore arm-length chemical resistant gloves, while the other half (8) did not wear gloves.

Dermal exposure was quantified using whole body dosimeters, and hand washes. For M/L/A, each participant wore a whole body dosimeter consisting of a long sleeved shirt and pants which were segmented and analyzed to determine potential exposures for the arms, upper legs, lower legs and torso. In addition, an undergarment consisting of one-piece cotton long underwear was collected to determine the penetration of chlorpryifos through outer clothing onto skin. Note that M/L/A replicates also wore a Tyvek (9 replicates) or cotton (8 replicates) coverall on top of the whole body dosimeter as personal protective clothing. A hat with a denim patch was analyzed to quantify head, neck, and face surface deposition.

Air samples were collected using a personal air sampling pump connected to a 37-mm GN-4 filter in series with a Chromosorb 102 tube. The filters were used to collect particulates while sorbent tubes were used to trap vapors. Samples were analyzed using GC-ECD.

As shown on Table 2, the average dermal absorbed dose (assuming a 3% dermal absorption rate) for the M/L/A wearing a single layer of clothes is 1.57 μg/kg/day, while the average inhalation dose is 0.45 μg/kg/day, based on passive dosimetry. The average dermal absorbed dose for the M/L/A wearing a double layer of clothes is 0.477 μg/kg/day, while the average inhalation dose is 0.45 μg/kg/day, based on passive dosimetry. These exposure estimates are for a 3 hour exposure measured in the study.

As shown on Table 2, the average dermal absorbed dose for the tarp pullers contacting one tarp without gloves is 0.081 μg/kg/day, while the average inhalation dose is 0.015 μg/kg/day, based on the passive dosimetry measurements. In addition, it was assumed that a worker could pull 8 tarps in one work day, which the study evaluated for construction of townhouses, or other homes under construction in close proximity. Therefore, the average 7 minute exposure for each tarp was multiplied by a factor of 8. The average dermal absorbed dose for the tarp pullers contacting eight tarps without gloves is 0.644 μg/kg/day, while the average inhalation dose is 0.122 μg/kg/day. The average dermal absorbed dose for the tarp puller wearing arm-length chemical-resistant gloves and contacting one tarp is 0.023 μg/kg/day, while the average inhalation dose is 0.021 μg/kg/day based on passive dosimetry. The average dermal absorbed dose for the tarp puller wearing arm-length chemical-resistant gloves and laying eight tarps is 0.177 μg/kg/day, while the average inhalation dose is 0.168 μg/kg/day based on passive dosimetry. It was assumed that these workers could be exposed for more than several months a year (i.e., long term).

(10) Post Construction Termiticide Use (Mixing/Loading and Applying) for Subterranean Termite Control (MRID No. 44729402)

Exposure estimates were derived from a chemical-specific study submitted by Dow AgroSciences in which workers were monitored during application of chlorpyrifos, as the termiticide Dursban® TC (43.9% ai) (EPA Reg. 62719-47), during post-construction termiticide treatments. HED evaluated this study in DP Barcode D252357 (Memorandum from G. Bangs to M. Hartman and D. Smegal, April 29, 1999). This study quantified potential pesticide applicator inhalation, dermal, and biological exposure to chlorpyrifos. The mixing/loading and application were monitored as a combined job function. Post-construction treatments were applied to various construction styles of residential housing (i.e., slab-on-grade, basement, crawlspace and

combinations thereof) in Virginia, Alabama, and Georgia. The applicators applied the termiticide at a rate of approximately 4 gallons of ~1 percent a.i. dilution (range 0.71-1.24%) per 10 linear feet using an average of 124 gallons per structure (range 40-325 gallons). Mixer/loader/applicator exposures during actual structural work using hand held spray gun or injection rod were monitored by passive dosimetry and limited biomonitoring of volunteer PCO. During applications, the PCOs wore the label-required protection, including a cotton coverall, chemically resistant nitrile gloves, a hat, protective eyewear and a half-facepiece respirator (if working in confined spaces). During mixing/loading, subjects wore additional PPE that consisted of chemically resistant footwear and an extra (second) coverall or a chemically resistant apron. There were a total of 15 replicates representing 9 different volunteers, from 3 companies in three cities. The study was conducted in compliance with most, but not all, OPPTS guidelines. The biomonitoring was very limited (5 replicates).

Higher inhalation exposures were encountered in basement and crawlspace applications than during slab treatments. The arithmetic mean inhalation dose is 1.48 μg/kg/day (normalized 70 kg body weight), and ranged from 0.17 to 3.18 μg/kg/day normalized body weight (N=14). The geometric mean dose is 0.91 μg/kg/day. The arithmetic mean value is based on data from 14 replicates because the fifteenth replicate had an unusually high dermal dose (50 μg/kg) resulting from an accident with a broken hose. Average inhalation exposure/hour (average 6.62 hours worked) was 15 μg/hr, with a range of 1.67 to 25.84 μg/hr.

During crawlspace treatments, workers experienced the greatest amount of dermal exposure to the head/neck (~48 percent of the dermal exposure on average). During slab and basement treatments, workers experienced the highest levels of dermal exposure to the legs (~63 percent and ~51 percent respectively on average). During basement treatments, exposure to the hands was greatest (~23 percent of total dermal exposure on average), however the number of application replicates was low (N=3). The arithmetic average dermal absorbed dose (N=14) based on passive dosimetry was 3.28 μg/kg/day with a range of 0.45 to 13.85 μg/kg/day, and excluding the 49.9 μg/kg/day dose due to one replicate being sprayed by a broken hose. The geometric mean absorbed dermal dose is 2.48 μg/kg/day, including the individual sprayed with a broken hose. These values utilize the current HED dermal absorption factor of three percent.

The total mean dose, calculated by addition of average inhalation and absorbed dermal doses, was estimated to be 4.76 μg/kg/day (normalized 70 kg body weight; N=14; range: 0.82 to 16.7 μg/kg/day), with inhalation representing 31 percent and dermal representing 69 percent of total dose measured via passive dosimetry. Total estimated dose (dermal and inhalation) for the 15th replicate was 50.50 μg/kg/day, which may be considered a worst-case exposure because it represents an equipment malfunction (i.e., broken hose).

Total mean absorbed chlorpyrifos dose of 4.27 μg/kg/day measured via the biological monitoring of the five workers in Georgia is slightly higher than the total absorbed chlorpyrifos dose calculated as the sum of 3 percent of total potential dermal dose (corrected for dermal absorption; measured via passive dosimetry) and potential inhalation dose for the same 5 replicates (3.24 μg/kg/day). Total absorbed dose was estimated directly by biomonitoring of the chlorpyrifos metabolite 3,5,6-TCP in the urine samples of five volunteer applicators at the Georgia location (it is unclear why the fifth replicate had the same weight as another, unless one volunteer was monitored for 2 days). The volunteers were told to avoid chlorpyrifos exposure for ten days

before the exposure application and for five days after the exposure. Each applicator collected all the urine voided on the day before application, the day of application, and for four consecutive days after initial exposure. The urine was collected at 12-hour intervals. The first day's collection was used as the baseline for correcting exposure calculations. The baseline chlorpyrifos ranged from 0.39 to 3.4 μg/kg(actual body weight)/day, with a mean of 1.1 μg/kg/day. The difference in estimated absorbed dose levels between biomonitoring and passive dosimetry may be due to various factors, including: incidental oral exposure to chlorpyrifos; field spike recovery from coveralls was consistently low (mean = 22 % ± 13%), so losses may not have been fully accounted for, or; subjects participating in biological monitoring experienced exposure to chlorpyrifos outside the study setting. (Note: the dose estimates were corrected for the low field recovery).

In at least three cases (replicates AL03, GA13, GA14), significantly more ai was reportedly applied than was mixed, and the study report does not explain how that is possible (i.e., presumably the applicators used other, previously prepared solution in addition to their own). For example, the amounts mixed for replicates AL03, GA13 and GA14 were 12, 4 and 3 lb ai/day, respectively compared to the amounts applied which were 16.5, 5.1 and 5 lb ai/day, respectively. A range of unit doses based on passive dosimetry were estimated by applying the mean exposure (normalized to μg/lb ai) of the 14 replicates to the high (32.7 lb), low (4.0 lb), and mean (10.72 lb) amount of material handled.

These data in MRID 44729402 are comparable with a similar scenario in PHED V1.1. There are 17 surrogate replicates in PHED monitored as a combined job function of mixing/loading/applying a termiticide via rod injection. The dermal exposures were monitored under single layer clothing and chemical resistant gloves. The dermal unit exposure is 360 μg/lb ai, adjusting for a 3% dermal absorption, the value is 11 μg/lb ai. The inhalation unit exposure was measured as 2.2 μg/lb ai (using the Subdivision U inhalation rate of 29 L/minute). Thus, the geometric mean biological monitoring unit exposure (D255669) of 16 μg/lb ai is consistent with the PHED best fit unit-exposure (dermal plus inhalation) of 13 μg/lb ai. The difference can be attributed to many variables (e.g., test subject hygiene, small sample sizes, variable dermal absorption rates based on amount deposited on skin, incidental oral ingestion, etc). However, there is close agreement.

(11) Paintbrush Application

HED has no data monitoring exposures to chlorpyrifos resulting from a paintbrush application to treat insect-infested wood. Therefore, exposures were evaluated based on data obtained from the Residential SOPs (12/18/97) for residential applicators (also from PHED V1.1). These data represent a worker painting a bathroom with a fungicide-treated latex paint. PCOs were not evaluated for this scenario because they are assumed to treat larger surfaces of wood with rollers or a spray, rather than a paintbrush. The unit exposure estimates for residential use assume that individuals wear short pants, short sleeves and no gloves. There is low to medium confidence in the dermal unit exposure estimates for residential exposure, which are based on 14 to 15 dermal replicates of grade C data, and 15 hand replicates of B grade data. There is medium confidence in the residential inhalation unit exposure estimates, which are based on 15 inhalation replicates of C grade data. HED conducted two evaluations, a high end scenario that assumed an individual could apply one gallon of diluted chlorpyrifos product (as Dursban 1-12 Insecticide; EPA Reg

No. 62719-56) to treat a large wood-infested area, and a more typical scenario which assumed the application of a quart of diluted product for a localized wood infestation. The label recommends diluting 5.33 oz of Dursban 1-12 Insecticide (12.6% ai; 1 lb ai/gallon) with 1 gallon of water. The resulting short-term dermal (potential exposure, not absorbed) and inhalation dose estimates for the high end scenario are 140 and 0.17 μg/kg/day, respectively, while the typical scenario doses estimates are 34 and 0.043 μg/kg/day, respectively. The dose estimates are presented on Table 2.

(12) Ornamental Application

HED has no data monitoring chlorpyrifos exposures to residents during mixing/loading or application to ornamentals (flowers, shrubs, evergreens, vines, shade and flowering trees and other ornamental plants). Therefore, exposures were evaluated based on data obtained from the Residential SOPs (12/18/97) (also from PHED V1.1) for mixing/loading and application activities. This assessment evaluates application via both a low pressure handwand and a hose end sprayer, which are assumed to be short-term scenarios for residents. A range of exposure estimates were evaluated for both application methods, the minimum, typical and maximum dilution rates of 1 oz, 4 oz and 1 quart of product per 3 gallons of water. The maximum rate is recommended for beetles. It was assumed that a resident would apply 5 gallons of diluted Dursban 1-12 Insecticide (EPA Reg No. 62719-56; 12.6% ai; 1 lb ai/gallon), in accordance with the residential SOPs for treatment of ornamental trees. The unit exposure estimates for residential use assume that individuals wear short pants, short sleeves and no gloves. For the hose-end sprayer, there is low confidence in dermal and inhalation unit exposure estimates, which are based on 8 dermal and inhalation replicates of C grade data, and 8 grade E hand replicates. For the low pressure handwand (liquid/open pour), there is low confidence in dermal unit exposure estimates, which are based on 9-80 dermal replicates of ABC grade data, and 70 hand replicates of all grades. There is medium confidence in the inhalation unit exposure estimates, which are based on 80 inhalation replicates of ABC grade data. As shown on Table 2, the dermal dose estimates range from 5.6 to 594 μg/kg/day, while the inhalation dose estimates range from 0.0018 to 0.18 μg/kg/day. The use of the low pressure handwand results in higher exposures.

Table 2 presents the exposure scenarios and exposure calculations using the above data sources for the residential uses of chlorpyrifos. Children are not included in this table since children would not be expected to apply this material, although they might be exposed after application.

(13) Mosquitocide Mixer/Loader/Applicator

HED has no data monitoring exposures to workers resulting from mixing/loading or applying chlorpyrifos-containing mosquitocide products. Therefore, exposures were evaluated based on agricultural data obtained from PHED V1.1. The PPE unit exposure estimates for handlers assume workers wear chemical-resistant gloves plus long-sleeve shirt and long pants (i.e., single layer clothing), except for aerial mixer/loader, where a double layer of clothing was assumed. Aerial and ground-based fogger applicators were not assumed to wear gloves. In addition, exposures were estimated for the use of engineering controls (i.e, closed systems for mixing, and enclosed cabs/cockpits). Only one application rate was assessed for aerial application (i.e., 0.023 lb ai/acre), while two application rates were assessed for ground-based fogger (i.e., 0.005 and

0.01 lb ai/acre) based on Mosquitomist One U.L.V label directions. Both short- and intermediate term exposure durations were assessed due to the absence of frequency data. This should be considered a range-finder assessment because agricultural exposure data were extrapolated for mosquitocide uses. Uncertainties arise from: (1) extrapolation of agricultural exposure data for similar uses related to mosquitocide uses (i.e,. mixer/loader and application of liquid products), (2) the large number of acres treated (i.e., 7500 acres for aerial and 3000 acres for ground-based fogger application), (3) frequency of use and exposure to workers, and (4) surrogate ground-based fogger exposure data are not available, and therefore, it was necessary to extrapolate from airblast exposure data.

3.2 Residential/Worker Postapplication Exposures & Assumptions

This section is organized into three main sections: (1) Indoor postapplication exposures; (2) Outdoor postapplication exposures; and (3) Scientific Literature Discussion.

EPA has determined that there is potential exposure to the general public (adults and children) following applications at residential and public sites - indoors and outdoors. Postapplication exposure data were required for chlorpyrifos in a reregistration DCI issued September 19, 1991 during the reregistration process, since, at that time, one or more toxicological criteria had been triggered for chlorpyrifos. The dose estimates are presented in Tables 3 and 4.

The following studies were submitted by the registrant:

- MRID No. 40094001 Airborne Chlorpyrifos Concentrations Measured During and Following Applications of Dursban TC Insecticide to Residential Dwellings. GH-P 1310.

- MRID No. 430135-01 Vaccaro et al. 1993. Chlorpyrifos: Exposure to Adults and Children Upon Reentry to Domestic Lawns, Following Treatment with a Chlorpyrifos-Based Mixture. Study ID No. DECO-HEH2.1-1-182(121).

- MRID No. 441671-01 Vaccaro et al. 1996. Chlorpyrifos: Exposure to Adults and Children Upon Reentry to Domestic Lawns, Following Treatment with a Chlorpyrifos-Based Granular Insecticide.

- MRID No. 444582-01 Byrne et al. 1998. Residential Exposure to Chlorpyrifos from Reentry to Structures Treated with Crack and Crevice and Spot Applications of Dursban Pro.

HED reviewed each of these studies and used the registrant-submitted data to estimate exposures to adults and children in residential settings. A brief summary of each study is provided below, with reference to HED's memorandum that provides a more detailed review and analysis of the study. As noted previously, a number of the registrant-submitted studies conducted biomonitoring by measuring urinary concentrations of the primary chlorpyrifos metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP), to estimate chlorpyrifos exposures. Prior to the studies, baseline urinary 3,5,6-TCP concentrations were determined in the study volunteers, and these baseline measurements were subtracted from the exposure-related 3,5,6-TCP concentrations

measured in the biomonitoring study. It is important to note that most individuals in the U.S., and nearly all the subjects in the Dow AgroSciences biomonitoring studies had low levels of urinary 3,5,6-TCP prior to study commencement, indicating a baseline exposure to chlorpyrifos, chlorpyrifos-methyl and/or 3,5,6-TCP as a result of dietary and/or residential/commercial/institutional exposures (Hill et al. 1995).

3.2.1 INDOOR POSTAPPLICATION EXPOSURES.

(1) Crack, Crevice and Spot Treatment of Kitchen and Bathroom (MRID 44458201) (Inhalation Exposures in a Treated Room)

Dow AgroSciences submitted a study designed to estimate chlorpyrifos exposure to adults conducting normal daily activities following treatment of the kitchen and bathroom of three houses with crack and crevice and spot applications of Dursban Pro insecticide (0.5% chlorpyrifos dilution with water) for cockroach control. HED evaluated this study in DP Barcode D242444 (Memorandum from D. Smegal to M. Hartman, December 3, 1998). Between 0.663 and 0.787 L of product (3.32 g to 3.94 g chlorpyrifos) was applied to the houses. Six adults (four women and two men), two from each of the three treated houses, were monitored 1 day pre-application and for 10 days postapplication via urine collection and analysis. The urine was analyzed for 3,5,6-TCP, the primary metabolite of chlorpyrifos. The volunteers were instructed to perform normal activities and to spend at least 12 hours per day inside the treated house. Air monitoring was conducted at two heights in the kitchen (site of application) and family room (adjacent room). In addition, deposition measurements and dislodgeable residues were collected in the family room and a bedroom of each treated house. Dislodgeable residues were measured on hard plastic toys (balls), and also on carpets in the family room and bedroom, to determine the amount of chlorpyrifos available for absorption.

Dislodgeable residues from the carpet and hard toy wipes in non-treated rooms were generally non detectable, indicating that the potential for dermal absorption is low. Based on the biomonitoring and environmental data collected in this study, the maximum one-day chlorpyrifos dose for the 6 adult volunteers, corrected for baseline exposure, is 0.39 μg/kg/day which is comparable to or less than estimated chlorpyrifos baseline doses of 0.1 - 0.86 μg/kg/day. The overall mean dose to the six volunteers is 0.18 μg/kg/day based on the biomonitoring data, while the mean baseline dose is 0.4 μg/kg/day. The method used to estimate exposures directly measures internal dose and does not differentiate between routes of exposure. However, the study results indicate that the predominant route of exposure is through inhalation.

Exposures to young children were estimated using air concentrations measured 15 inches above the floor, and standard EPA default exposure assumptions (i.e., breathing rate, body weight and duration of exposure). Dermal and oral exposures were assumed to be negligible based on an absence of detectable dislodgeable residues in the carpet wipes or on hard plastic toy wipes in all three houses (in untreated rooms), except for a negligible quantity of residue detected on a hard ball in the family room of house #3. For example, if a child ingested the entire residue present on the toy, the resulting dose would be approximately 0.089 μg or 0.006 μg/kg, which is negligible relative to the estimated exposures from inhalation (10 -100 fold less). The estimated 10 day mean doses to children are 0.08, 0.28 and 0.22 μg/kg/day, while the highest one-day

doses are 0.27, 0.76 and 0.61 μg/kg/day for houses #1, #2 and #3, respectively. These exposure estimates are also within the background range observed for adults. The one day exposure estimates are conservative, because they assume a child could spend 21 hours exclusively in a treated room. The 21 hours/day estimate represents the 50th percentile for time spent at home for children ages 1-4 years old according to USEPA Exposure Factor Handbook (1997). However, this study did not evaluate chlorpyrifos residues on soft plush toys, which could also contribute to child exposure. In addition, the study did not adequately evaluate potential chlorpyrifos residues on the floor or other surfaces in treated rooms as no dislodgeable residues were collected in the kitchen or bathroom (only in adjacent, untreated rooms). A few deposition measurements were collected in the kitchen and bathroom (total of seven from all three houses) from 0-2 hours post treatment. However, these data are inadequate for risk assessment because of the small number of measurements (from 3 houses), and because deposition measurements increased over time in untreated rooms (up to 10 days), therefore, the 0-2 hour levels are unlikely to reflect potential longer-term exposures. For example, it should be noted that the highest deposition in an adjacent untreated room(2.298 μg/100 cm^2) was higher than 5 of the 7 treated room 0-2 hour deposition measurements.

In conclusion, these data demonstrate that exposures to adults following crack, crevice and spot applications of chlorpyrifos in the kitchen and bathroom by a licensed applicator are comparable to typical background exposures levels based on biomonitoring data where adults were in the house 12 hours per day. The adult biomonitoring data are insufficient to characterize child exposures due to the vastly different activity patterns of adults and children (i.e., children crawl, have more hand to mouth activity, and typically spend more time at home, etc). These data do not support the use of crack and crevice or spot treatment in bedrooms, living rooms, closets, day care centers, schools, playhouses, on furniture or draperies, or in other rooms that could result in higher exposure to individuals, particularly children. In addition, these data do not support the indoor application of up to 1% Dursban Pro for the treatment of exposed wood surfaces, voids and channels in damaged wood, wall voids, and junctions between wood and foundation that are currently listed on the label.

In addition, low air concentrations of chlorpyrifos were still present in all three homes 10 days post treatment, however some of the current labels allow re-treatment every 7 days. In one house, the highest daily average air concentrations were detected on the 6th day following chlorpyrifos treatment, indicating possible sinks and resuspension. The results of this assessment are presented in Table 3. This study has not addressed the possible cumulative effects of multiple treatments over time, although, additional information was requested from the registrant to support a 7 day re-treatment interval as proposed in the Dow AgroSciences submission (MRID 44331901). DAS submitted additional analysis of the same air measurements to demonstrate that the potential for cumulative effects was minimal. HED however, believes additional data are necessary to alleviate our concerns pertaining to frequent indoor re-treatments. HED requests <u>treated room residue data</u> for floors, furniture and other surfaces available for contact by children for both chlorpyrifos, and its primary degradation metabolite, 3,5,6-TCP following multiple treatments, in addition, to chlorpyrifos air measurements in treated rooms following multiple treatments (i.e., at a minimum 3 treatments 7 days apart). Residue data for 3,5,6-TCP are important due to the potential for accumulation and persistence of this environmental degradate.

(2) Crack and Crevice Treatment of Other Rooms Using Residential SOPs (Dermal and Oral Exposures in an Untreated Room)

HED also assessed potential short-term exposures to adults and children using the updated Residential SOPs (2000), to supplement the evaluation of crack and crevice treatment based on the registrant-submitted biomonitoring study discussed above. This additional assessment was conducted due to the concerns that the registrant-submitted biomonitoring did not adequately evaluate exposures that could occur following treatment of baseboards and window and door frames in family rooms, bedrooms, living rooms or other treatments that could occur in schools, day care centers, playhouses, or the many other buildings listed on the labels.

The highest deposition residue detected in the untreated