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

OPP

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 14, 1999

MEMORANDUM

SUBJECT: REVISED OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT FOR **TRIPHENYLTIN HYDROXIDE (TPTH)**. REVISION REFLECTS MODIFIED UNIT EXPOSURE VALUE FOR MIXING/LOADING WETTABLE POWDER IN WATER-SOLUBLE BAGS.

FROM: Kelly O'Rourke, Biologist
Registration Action Branch III
Health Effects Division (7509C)

TO: Sarah Law, Risk Assessor
Reregistration Branch III
Health Effects Division (7509C)

THRU: Steve Dapson, PhD, Branch Senior Scientist
Registration Action Branch III
Health Effects Division (7509C)

Please find the revised review of TPTH.

DP Barcode:	259319
Pesticide Chemical Codes:	083601
EPA Reg Nos.:	1812-244, 1812-279, 1812-350, 1812-351, 5204-86, 45639-170, 45639-171, 45639-186, 55146-71, 55146-72, ME97000100, MI97000100, MN97000300, ND97000400, NE98000100, OR97002100, WA97003500, WI97000500
EPA MRID No.:	43599401, 40816901, 43557401, and 42507801

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PHED: Yes, Version 1.1 (August, 1998)

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0.0 SUMMARY OF SIGNIFICANT ITEMS

The following issues need to be considered before the TPTH RED is finalized.

- Chemical-specific exposure and transferable residue data were used to complete this assessment. Most of these data have undergone at least primary review and have been considered acceptable, however, the studies are several years old and may require a more recent evaluation to ensure that adjustments were made according to our current policies.

- A couple of labels (Reg Nos. 45639-170 and 45639-186) indicate an REI of 24 hours, however, the REI stated by the registrants at the SMART meeting is 48 hours. The 48-hour REI (which is indicated on the other labels) is consistent with the WPS requirements for primary eye irritation (tox category I). These may be old labels that have since been updated to reflect the 48-hour REI, but some investigation is recommended.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE AND RISK ASSESSMENTS

(RED SECTION III, PART 3)
EXPOSURE AND RISK ASSESSMENT/CHARACTERIZATION

1.0 BACKGROUND

1.1 Purpose

In this document, which is for use in EPA's development of the triphenyltin hydroxide (TPTH) Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to TPTH.

1.2 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For TPTH, both criteria are met.

1.3 Summary of Toxicity Concerns Relating to Occupational and Residential Exposures

1.3.1 Acute Toxicology Categories

Table 1 below presents the acute toxicity categories as outlined in the TPTH - Report of the Hazard Identification Assessment Review Committee (November 13, 1998).[1]

Table 1: Acute Toxicity Categories for TPTH

Guideline Number	Toxicity Category	Dose
81-1	acute oral (II)	165 mg/kg
81-2	acute dermal (II)	1600 mg/kg
81-3	acute inhalation (I)	60.3 µg/L
81-4	primary eye irritation (I)	Corrosive
81-5	primary skin irritation (III)	PIS = 2.8
81-6	dermal sensitization (non-sensitizing)	Negative

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1.3.2 Other Endpoints of Concern

The Report of the Hazard Identification Assessment Review Committee (HIARC) for TPTH, dated November 13, 1998, indicates that there are toxicological endpoints of concern for TPTH. The endpoints used in assessing the risks for TPTH are presented in the following table.

Table 2: Endpoints for Assessing Occupational and Residential Risks for TPTH[1]

Exposure Routes	Exposure Duration	Dose (mg/kg/day)	Effect	Study	Uncertainty Factor	Comment
Dermal	Short-term (1-7 days)	NOAEL 3.0	No effect observed at the highest dose tested	Dermal developmental toxicity (rabbit)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Dermal	Intermediate-term (1 week to several mos)	NOAEL 3.0	No effect observed at the highest dose tested	Dermal developmental toxicity (rabbit)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Inhalation	Any time period	NOAEL 0.092[a]	Death following lung lesions	Subchronic inhalation study (rat)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation, intra-species variability(10x)
Dermal & Inhalation	Cancer Risk	Oral Q_1* 1.83 $mg/kg/day^{-1}$	Probable human carcinogen. Pituitary, testicular, and liver tumors	Oral Cancer (Rat and mouse)	NA	A dermal absorption of 10% should be used. Based on comparison between rabbit oral and dermal studies. Inhalation absorption assumed to be 100%.

[a] Inhalation dose in mg/L was converted to mg/kg/day using the following equation:
Dose (mg/kg/day) = (NOAEL (0.00034 mg/L) * Respiration rate of a young adult Wistar rat (8.46 L/hr) * Study daily exposure duration (6 hr/day)) / Body weight of a young adult Wistar rat (0.187 kg)

1.4 Incident Reports

Epidemiological Information

The following data bases have been consulted for the poisoning incident data on the active ingredient TPTH (PC Code: 083601):

1. OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies

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and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.

2. Poison Control Centers - as the result of Data-Call-Ins issued in 1993, OPP received Poison Control Center data covering the years 1985 through 1992 for 28 organophosphate and carbamate chemicals. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.

3. California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.

4. National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

Conclusions

Relatively few incidents of illness have been reported due to TPTH.

1.5 Summary of Use Patterns and Formulations

1.5.1 Occupational-Use and Homeowner-Use Products

At this time products containing TPTH are intended for occupational use only (i.e., no residential uses). Occupational uses include pecans, sugar beets, and potatoes.[2,3]

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1.5.2 Type of pesticide/target pests

TPTH, Triphenyltin Hydroxide, is a restricted use contact (i.e., not systemic) fungicide used to control pest infestations on sugar beets, potatoes and pecans. Some of the pests controlled by TPTH include: Cercospora Leafspot on sugar beets; Early and Late Blight, and suppression of the Colorado Potato Beetle on potatoes; Scab, Brown Leafspot, Downy Spot, Powdery Mildew, Liver Spot, Sooty Mold and Leaf Blotch on pecans.[3]

1.5.3 Formulation types and percent active ingredient

TPTH is formulated as a technical product (96 percent active ingredient), a wettable powder in water-soluble bags (47.5 and 80 percent active ingredient), and a flowable (liquid) concentrate (4.72 and 40 percent active ingredient). According to the labels for the flowable concentrate, a mechanical transfer system is required for all mixing and/or loading of the product. The mechanical transfer system is defined on the label as a mechanism capable of removal of the product from the shipping container and transfer to mixing tanks and/or application equipment to prevent worker exposure to the pesticide. In addition, a closed system for mixing/loading is required for aerial application. The closed system must be capable of removing the pesticide from the shipping container, rinsing the container and transferring the pesticide and rinsate into mixing tanks and/or application equipment.[2,3]

1.5.4 Registered use sites

Occupational-use sites. TPTH has been registered for occupational-use on pecans, potatoes, and sugar beets.

Non-occupational-use sites. There are currently no potential residential or non-occupational use sites.

1.5.5 Application Rates[2,3,4]

- **Pecans:** The maximum application rate for pecans is 0.375 lb ai/acre, and the typical application rate is 0.25 lb ai/acre.
- **Potatoes:** The maximum application rate for potatoes is 0.1875 lb ai/acre, and the typical application rate is 0.125 lb ai/acre.
- **Sugar beets:** The maximum application rate applied to sugar beets is 0.25 lb ai/acre, and the typical application rate is 0.125 lb ai/acre.

1.5.6 Methods and Types of Equipment used for Mixing, Loading, and Application[2,3,4]

- **Pecans:** Airblast sprayer for orchards is the primary treatment method for pecans, however, aircraft (fixed-wing and helicopter) are also used.

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- **Potatoes:** Equipment used on potatoes includes chemigation systems, groundboom sprayer, and aircraft (fixed-wing and helicopter).

- **Sugar beets:** Equipment includes groundboom sprayer and aircraft (fixed-wing and helicopter).

1.5.7 Timing and Frequency of Applications[2,3,4]

- **Pecans:** The maximum number of applications to pecans per season is 10, with an interval range of 14-28 days. Typically, 4 to 5 applications are made per season.

- **Potatoes:** TPTH may be applied to potatoes up to 6 times per season, at 7-day intervals. The typical number of applications is 2 to 3 per season.

- **Sugar beets:** TPTH is typically applied to sugar beets 2 times per season. The labels state that applications may be made at 10- to 14-day intervals, for a maximum of four times per season, however, an increase to five times per season is planned by the registrant.[5]

2.0 OCCUPATIONAL EXPOSURES AND RISKS

EPA has determined, based on current use patterns, that there are potential exposures to workers handling TPTH products, as well as to workers who come into contact with treated surfaces following applications of TPTH products.

2.1 Handler Exposures & Risks

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with TPTH.

2.1.1 Handler Exposure Scenarios

Based on the use patterns, 10 major handler exposure scenarios were identified for TPTH:

(1a) mixing, loading liquids for aerial/chemigation application;
(1b) mixing, loading liquids for groundboom application;
(1c) mixing, loading liquids for orchard airblast sprayer application;
(2a) mixing, loading wettable powder in water-soluble bags (WSB) for aerial/chemigation application;
(2b) mixing, loading wettable powder in water-soluble bags (WSB) for groundboom application;
(2c) mixing, loading wettable powder in water-soluble bags (WSB) for orchard airblast sprayer application;
(3) applying sprays with fixed-wing aircraft;

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(4) applying sprays using a groundboom sprayer;
(5) applying to orchards with an airblast sprayer;
(6) mixing and loading liquid and applying sprays with a groundboom sprayer;
(7) mixing and loading liquid and applying sprays to orchards with an airblast sprayer;
(8) mixing and loading wettable powder in water-soluble bags (WSB) and applying sprays with a groundboom sprayer;
(9) mixing and loading wettable powder in water-soluble bags (WSB) and applying sprays to orchards with an airblast sprayer; and
(10) flagging during aerial spray application.

2.1.2 Handler Exposure Scenarios, Data, and Assumptions

Two studies, which contain chemical-specific data for assessing human exposure during pesticide handling activities, were submitted to the Agency in support of the reregistration of TPTH:

Mixing/Loading Wettable Powder in Water-Soluble Bags (MRID# 43599401)

The following is a summary of the review of the submission from the TPTH task force, as excerpted from "Revised Occupational Risk Assessment for the Use of TPTH on Pecans" (Lewis, P. and Scheltema, C., 1997).[6]

"The water soluble pack study was conducted in three pecan groves in Georgia (Odiott, 1996; Brennan and Leighton, 1996). TPTH SUPER-TIN 80WP in water soluble packs was open loaded into a 500 gallon tank of a tractor or a self powered airblast applicator at a rate of 0.375 lb ai in 100 gallons of water per acre. Fifteen replicates were monitored in the study. Monitoring times ranged from 2 to 10 minutes. Each worker handled 1.9 lbs ai/replicate, enough active ingredient to treat only 5 acres at the maximum label rate. [BEAD estimates that 40 acres can typically be treated per day.]

Dermal exposure was monitored using cotton gauze pad dosimeters worn beneath clothing. Hand exposure was monitored using nylon gloves with chemical resistant gloves worn over these gloves. Inhalation exposure was monitored using nylon filters attached to personal air pumps.

Several discrepancies were noted in the study and were addressed in a subsequent submission by the registrant. OREB has reviewed the registrant's submission and has concluded that the mixer/loader study is acceptable to fulfill Subdivision U of the Pesticide Assessment Guidelines (Carleton, 1996). Even though the amended study was considered acceptable, several inappropriate extrapolations were employed. First, the face areas were incorrectly adjusted from 1300 cm^2 down to 500 cm^2, thus utilizing a protection factor to adjust for the wearing of a hat. OREB does not apply a protection factor for the use of a hat. Second, the registrant incorrectly normalized exposure according to the body weight of the test subjects, rather than using the standard body weight of 70 kg. These errors were corrected in OREB's analysis.

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The majority of the field sample results fell below the limit of detection (LOD [LOD = 0.2 µg/sample]). No residues were detected in any of the air samples; only the hand and thigh samples consistently showed any measurable residues. The basis for the low amount of residues recovered was due to the small amount of material handled in the study (one water-soluble pack per 500 gallon tank, per replicate). HED originally estimated non-detectable residues as ½ the limit of quantification (LOQ [LOQ = 1.0 µg/sample]). HED now estimates these residues as ½ the LOD."

The corrected mixing/loading unit exposures for dermal and inhalation routes of exposure are 46.4 µg/lb active ingredient and 0.071 µg/lb active ingredient, respectively.

Application: Airblast Sprayer (MRID# 40816901)

The Agency's review of this submission, "Risk Assessment of Workers Exposed to Triphenyltin Hydroxide Fungicide Applied to Row Crops by Ground Boom Sprayer and Aircraft, and to Pecans by Airblast Sprayers" (Knott, S., 1990), indicated that the data were applicable to airblast sprayer exposure, but only for an enclosed cab tractor. Groundboom sprayer and aircraft exposure data were not considered valid. Although mixer/loader exposures were also evaluated, these data are not applicable because open pour practices are no longer used.

The airblast sprayer study consisted of sixteen replicates, with workers wearing long-sleeved shirts, long pants, and chemical-resistant gloves. The application rates ranged from 0.39 to 0.45 pounds active ingredient per acre, with the total number of acres treated ranging from 6 to 12. The sampling time for dermal exposure ranged from one to two hours, while inhalation exposure sampling was not conducted. The total dermal unit exposure from the study was estimated to be 0.021 mg/lb ai for worker applying sprays with an enclosed cab airblast sprayer.

It is the policy of HED to combine submitted chemical-specific data, when possible, with that from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions.[7] The data from the exposure study for wettable powder in water-soluble bags were combined with PHED data for this scenario. [Note: In the previous version of this document, dated May 6, 1999, these study data were used solely to estimate unit exposure because, due to software compatibility issues, HED did not have the capability to merge these data with PHED data.] The airblast sprayer exposure data were combined with PHED data for the enclosed cab scenario.

For scenarios that do not have chemical-specific data submissions, it is the policy of the HED to use data from PHED to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.[7]

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

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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 scenarios (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 nor 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 data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table 3. 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.[8] This surrogate exposure guide serves as the basis for this assessment.

There are three basic risk mitigation approaches considered appropriate for controlling occupational exposures. These include administrative controls, the use of personal protective equipment or PPE, and the use of engineering controls. Occupational handler exposure assessments are 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 or cancer risk. The baseline clothing/PPE 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 gloves 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,

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attempt to reduce or eliminate the potential for exposure. Examples of commonly used engineering controls include closed tractor cabs, closed mixing/loading/transfer systems, and water-soluble packets. [Note: Administrative controls may include methods such as altering application rates for handler exposure scenarios. These measures are typically not assumed to

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Table 3: Exposure Scenario Descriptions for the Use of TPTH

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Descriptors			
Mixing/Loading Liquid Formulations - closed mixing system (1a/1b/1c)	PHED V1.1	350 acres for chemigation of potatoes; 400 acres for aerial application to pecans; 1,000 acres for aerial application to potatoes and sugar beets; 150 acres for groundboom application; and 40 acres for airblast sprayer application.	**Baseline:** Not applicable. Only formulated to be used with a closed mixing/loading system. See engineering controls. **PPE:** Not applicable. Only formulated to be used with a closed mixing/loading system. See engineering controls. **Engineering Controls:** Mechanical transfer method. Hands, dermal and inhalation unit exposures = AB grades. Hands = 31 replicates; dermal = 16 to 22 replicates, and inhalation = 27 replicates. High confidence in dermal, hand and inhalation data. Gloves were worn during the use of the engineering controls.
Mixing/Loading Wettable Powders - water soluble bags (2a/2b/2c)	MRID: 43599401 with the incorporation of PHED	350 acres for chemigation of potatoes; 400 acres for aerial application to pecans; 1,000 acres for aerial application to potatoes and sugar beets; 150 acres for groundboom application; and 40 acres for airblast sprayer application.	**Baseline:** Not applicable. Only formulated as a water-soluble bag. See engineering controls. **PPE**: Not applicable. Only formulated as a water-soluble bag. See engineering controls. **Engineering Controls**: Water soluble bags. Hands, dermal and inhalation unit exposures = AB grades. Hands = 24 replicates; dermal = 6 to 30 replicates, and inhalation = 15 replicates. Medium confidence in dermal, hand and inhalation data. Gloves were worn during the use of the engineering controls.
Applicator Descriptors			
Applying with a Fixed-Wing Aircraft (3)	PHED V1.1	400 acres for aerial application to pecans, and 1,000 acres for aerial application to potatoes and sugar beets	**Baseline:** No data **PPE:** No data **Engineering Controls:** Hands = AB grade, dermal and inhalation = ABC grade. Medium confidence in hands/dermal and inhalation data. Hands = 34 replicates, dermal = 24-48 replicates, and inhalation = 23 replicates.

Table 3: Exposure Scenario Descriptions for the Use of TPTH (continued)

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Applying Sprays with a Groundboom Sprayer (4)	PHED V1.1	150 acres	**Baseline:** Hand, dermal, and inhalation = AB grades. Hands = 29 replicates, dermal = 23 to 42 replicates, and inhalation = 22 replicates. High confidence in hand, dermal, and inhalation data. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing, and an 80% PF to account for the use of a dust mist respirator, respectively. Hands data are ABC grades with 21 replicates. Medium confidence in hands, and dermal data. **Engineering Controls:** Hands and dermal = ABC grade, inhalation = AB grade. Hands = 16 replicates, dermal = 20-31 replicates, inhalation = 16 replicates. Medium confidence in hands and dermal data, and high confidence in inhalation data.
Applying to Orchards with an Airblast Sprayer (5)	PHED V1.1 with the incorporation of MRID# 40816901 (for engineering control only)	40 acres	**Baseline**: Hand, dermal and inhalation are AB grade. Hands = 22 replicates, dermal = 32 to 49 replicates, and inhalation = 47 replicates. High confidence in hand, dermal and inhalation data. **PPE**: Hands and dermal = AB grade. Hands = 18 replicates, dermal = 31-48 replicates. High confidence in hands and dermal data. A 5-fold (80% PF) was applied to baseline inhalation data to account for use of dust-mist respirator. **Engineering Controls**: Dermal = AB grade, inhalation = ABC grade. High confidence in dermal data but low confidence in inhalation data. Inhalation = 9 replicates, dermal = 20-30 replicates, hand = 20 replicates. Gloves were worn during the use of the engineering controls.
Mixer/Loader/Applicator Descriptors			
Mixing/Loading Liquids and Applying Sprays with a Groundboom Sprayer (6)	PHED V1.1	150 acres	Combination of data from scenarios 1 and 4.
Mixing/Loading Liquids and Applying Sprays to Orchards with an Airblast Sprayer (7)	PHED V1.1	40 acres	Combination of data from scenarios 1 and 5.
Mixing/Loading Wettable Powder (WSB) and Applying Sprays with a Groundboom Sprayer (8)	PHED V1.1	150 acres	Combination of data from scenarios 2 and 4.

Table 3: Exposure Scenario Descriptions for the Use of TPTH (continued)

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixing/Loading Wettable Powder (WSB) and Applying Sprays to Orchards with an Airblast Sprayer (9)	PHED V1.1	40 acres	Combination of data from scenarios 2 and 5.

Table 3: Exposure Scenario Descriptions for the Use of TPTH (continued)

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Flagger Descriptors			
Flagging Spray Applications (10)	PHED V1.1	350 acres	**Baseline:** Hands, dermal and inhalation data = AB grades. High confidence in dermal, hands and inhalation. Hands = 30 replicates, Inhalation = 28 replicates, and dermal = 18-28 replicates. **PPE:** Dermal and hands = AB grade. Hands = 6 replicates, dermal = 18-28 replicates. Low confidence for dermal and hands data. A 80% PF was applied to baseline data to represent dust mist respirator. **Engineering Controls:** The same dermal and inhalation data are used as for the baseline coupled with a 98% protection factor to represent an enclosed truck.

[a] All *Standard Assumptions* are based on an 8-hour work day as estimated by BEAD and HED.[4]

[b] All handler exposure assessments in this document are based on the "Best Available" data as defined by the PHED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments). Best available grades are assigned to data as follows: matrices with A and B grade data (i.e., Acceptable Grade Data) and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories 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
Low = any run that included D or E grade data or has less than 15 replicates per body part.

be feasible in completing handler exposure assessments because of the effect on efficacy that such an alteration could have. When other mitigation options are not available, EPA may explore administrative controls in conjunction with the registrant.]

The following assumptions and factors were used in order to complete this exposure assessment:

- Average body weight of an adult handler is 70 kg. This body weight is used in the inhalation and cancer assessments. A body weight of 60 kg is used in the short- and intermediate-term dermal assessments because the NOAEL is based on a developmental study.

- Average work day interval represents an 8 hour workday (e.g., the acres treated or volume of spray solution prepared in a typical day).

- Daily acres to be treated in each scenario. These are based on use information gathered by the Biological and Economic Analysis Division (BEAD)[4]. The typical daily acres treated are as follows: 40 acres for airblast application to pecan orchards, 150 acres for groundboom application to potatoes and sugar beets, 1,000 acres for aerial application to potatoes and sugar beets, and 400 acres for aerial application to pecan orchards (this is rarely done). Specific data were not available for private growers using chemigation for potatoes, or for flaggers during aerial application; therefore, the Exposure Science Advisory Council estimate of 350 acres (for aerial and chemigation applications in agricultural settings) was used as a default. Although a typical aerial application of TPTH treats 1,000 acres, it is likely that an automated means of flagging, rather than human flaggers, would be employed for applications to greater than 350 acres.

- For the non-cancer assessment, calculations were completed using the maximum application rates for specific crops recommended by the available TPTH labels. "Typical" application rates (from BEAD, see Section 1.5.5) were also used in the calculations in cases where maximum rates yielded risks that exceed the appropriate level of concern (i.e., MOE < 100 or Cancer risk > 1E-4). Typical application rates were used in the calculations for the cancer assessment.

- Due to a lack of scenario-specific data, HED often must calculate unit exposure values using generic protection factors (PF) to represent various risk mitigation options (i.e., the use of personal protective equipment (PPE) and engineering controls). PPE protection factors include those representing a double layer of clothing (50 percent PF for body exposure), chemical resistant gloves (90 percent PF for hand exposure), and respiratory protection (80 percent PF for use of dust/mist mask).

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2.1.3 Handler Exposure and Non-Cancer Risk Estimates

Handler exposure assessments are completed by EPA using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve a margin of exposure that is 100 or greater. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, and no chemical-resistant gloves. The following tables present exposure and risk estimates for the handling of TPTH. Table 4 presents the inhalation and short- and intermediate-term dermal exposures at baseline. Table 5 presents the short- and intermediate-term dermal risks for baseline and with the use of PPE or engineering controls. Please note that for private growers, only the short-term endpoint is applicable because exposures are not expected to exceed seven days, whereas for commercial applicators, both the short- and intermediate-term endpoints are applicable. For TPTH, the presentation of these risks in Table 5 is simple because the short- and intermediate-term endpoints are the same value. Table 6 presents the inhalation risks for baseline and when using PPE or engineering controls.

In calculations of inhalation and short- and intermediate-term dermal risks, potential daily exposures were calculated using the following formulas:

$$\textit{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) = \textit{Inhalation Unit Exposure}\left(\frac{\mu g\ ai}{lb\ ai}\right) \times \textit{Conversion Factor}\left(\frac{1mg}{1{,}000\ \mu g}\right) \times \textit{Use Rate}\left(\frac{lb\ ai}{A}\right) \times \textit{Daily Acres Treated}\left(\frac{A}{day}\right)$$

$$\textit{Daily Dermal Exposure}\left(\frac{mg\ ai}{day}\right) = \textit{Dermal Unit Exposure}\left(\frac{mg\ ai}{lb\ ai}\right) \times \textit{Use Rate}\left(\frac{lb\ ai}{A}\right) \times \textit{Daily Acres Treated}\left(\frac{A}{day}\right)$$

The potential doses were calculated using the following formula:

$$\textit{Daily Dose}\left(\frac{mg\ ai}{kg/day}\right) = \textit{Daily Exposure}\left(\frac{mg\ ai}{day}\right) \times \left(\frac{1}{\textit{Body Weight (kg)}}\right)$$

For TPTH, the short- and intermediate-term dermal doses were calculated using a 60 kg body weight, while the inhalation dose uses a 70 kg body weight in the calculations. A dermal absorption rate was not necessary because the dermal endpoints were based on a dermal study. The inhalation endpoint was based on an inhalation study, therefore, an absorption rate is not applicable in the dose calculation.

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Table 4. Occupational Inhalation and Short- and Intermediate-term Dermal Exposures from TPTH

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e]	Baseline Daily Dermal Exposure[f] (mg/day)	Baseline Daily Inhalation Exposure[g] (mg/day)
Mixer/Loader Exposure							
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	See Engineering Control	See Engineering Control	0.375	Pecans	400 acres	See Engineering Control	See Engineering Control
			0.1875	Potatoes	1,000 acres		
			0.25	Sugar beets	1,000 acres		
			0.125 (Typ)	Sugar beets	1,000 acres		
Mixing/Loading Liquids for Groundboom Application (1b)			0.1875	Potatoes	150 acres		
			0.25	Sugar beets	150 acres		
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)			0.375	Pecans	40 acres		
Mixing/Loading Wettable Powder (WSB) for Aerial/Chemigation Application (2a)	See Engineering Control	See Engineering Control	0.375	Pecans	400 acres	See Engineering Control	See Engineering Control
			0.25 (Typ)	Pecans	400 acres		
			0.1875	Potatoes	1,000 acres		
			0.125 (Typ)	Potatoes	1,000 acres		
			0.25	Sugar beets	1,000 acres		
			0.125 (Typ)	Sugar beets	1,000 acres		
Mixing/Loading Wettable Powder (WSB) for Groundboom Application (2b)			0.1875	Potatoes	150 acres		
			0.25	Sugar beets	150 acres		
Mixing/Loading Wettable Powder (WSB) for Orchard Airblast Sprayer Application (2c)			0.375	Pecans	40 acres		
Applicator Exposure							
Applying Sprays with a Fixed-Wing Aircraft (3)	No Data See Eng. Cont.	No Data See Eng. Cont.	0.375	Pecans	400 acres	See Engineering Control	See Engineering Control
			0.1875	Potatoes	1,000 acres		
			0.25	Sugar beets	1,000 acres		

Table 4. Occupational Inhalation and Short- and Intermediate-term Dermal Exposures from TPTH (continued)

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e]	Baseline Daily Dermal Exposure[f] (mg/day)	Baseline Daily Inhalation Exposure[g] (mg/day)
Applying Sprays with a Groundboom Sprayer (4)	0.014	0.74	0.1875	Potatoes	150 acres	0.39	0.021
			0.25	Sugar beets	150 acres	0.53	0.028
Applying Sprays to Orchards with an Airblast Sprayer (5)	0.36	4.5	0.375	Pecans	40 acres	5.4	0.068
			0.25 (Typ)	Pecans	40 acres	3.6	0.045
Mixer/Loader/Applicator Exposure							
Mixing/Loading Liquids and Applying Sprays with a Groundboom Sprayer (6)	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	0.1875	Potatoes	150 acres	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control
			0.25	Sugar beets	150 acres		
Mixing/Loading Liquids and Applying Sprays to Orchards with an Airblast Sprayer (7)			0.375	Pecans	40 acres		
Mixing/Loading Wettable Powder (WSB) and Applying Sprays with a Groundboom Sprayer (8)			0.1875	Potatoes	150 acres		
			0.25	Sugar beets	150 acres		
			0.125 (Typ)	Sugar beets	150 acres		
Mixing/Loading Wettable Powder (WSB) and Applying Sprays to Orchards with an Airblast Sprayer (9)			0.375	Pecans	40 acres		
Flagger Exposure							
Flagging Spray Applications (10)	0.011	0.35	0.375	Pecans	350 acres	1.4	0.046
			0.1875	Potatoes	350 acres	0.72	0.023
			0.25	Sugar beets	350 acres	0.96	0.031

Footnotes:

a Baseline dermal unit exposure reflects long pants, long-sleeved shirt, no gloves, open mixing/loading, and open cab. Reference to engineering controls is made because TPTH is formulated only to be used with a closed mixing/loading system (liquid) or as a water-soluble bag (wettable powder).

b Baseline inhalation unit exposure reflects no respiratory protection. Reference to engineering controls is made because TPTH is formulated only to be used with a closed mixing/loading system (liquid) or as a water-soluble bag (wettable powder).

c Application rates: Unless otherwise stated, all rates are maximum rates and come from values found in the LUIS report and on TPTH labels. In cases where the maximum rate yields a risk that exceeds the level of concern (i.e., MOE < 100), calculations are also performed using the typical rate (indicated by "Typ") which comes from BEAD.

d Crop Type or Target provides a description of the intended uses of various products containing TPTH.

e Amount Treated Per Day values are from BEAD.

f Baseline Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day).

Table 4. Occupational Inhalation and Short- and Intermediate-term Dermal Exposures from TPTH (continued)

g Baseline Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day)

Table 5. Occupational Short- and Intermediate-term Dermal MOEs for TPTH at Baseline and with Mitigation Measures

Exposure Scenario (Scen. #)	Crop Type or Target	Baseline Daily Dermal Dose[a] (mg/kg/day)	Baseline Dermal MOE[b]	Risk Mitigation Measures					
				Additional PPE[c]			Engineering Controls[d]		
				Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose[e] (mg/kg/day)	Dermal MOE[b]	Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose[e] (mg/kg/day)	Dermal MOE[b]
Mixer/Loader Risk									
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	Pecans	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	0.0086	0.022	140
	Potatoes							0.027	110
	Sugar beets							0.036	84
	Sugar beets (Typ)							0.018	170
Mixing/Loading Liquids for Groundboom Application (1b)	Potatoes							0.004	740
	Sugar beets							0.0054	560
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)	Pecans							0.0022	1,400
Mixing/Loading Wettable Powder (WSB). for Aerial/Chemigation Application (2a)	Pecans	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	0.022	0.055	55
	Pecans (Typ)							0.037	82
	Potatoes							0.069	44
	Potatoes (Typ)							0.046	65
	Sugar beets							0.092	33
	Sugar beets (Typ)							0.046	65
Mixing/Loading Wettable Powder (WSB) for Groundboom Application (2b)	Potatoes							0.010	290
	Sugar beets							0.014	220
Mixing/Loading Wettable Powder (WSB) for Orchard Airblast Sprayer Application (2c)	Pecans							0.0055	550

Table 5. Occupational Short- and Intermediate-term Dermal MOEs for TPTH at Baseline and with Mitigation Measures (continued)

Exposure Scenario (Scen. #)	Crop Type or Target	Baseline Daily Dermal Dose[a] (mg/kg/day)	Baseline Dermal MOE[b]	Risk Mitigation Measures					
				Additional PPE[c]			Engineering Controls[d]		
				Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose[e] (mg/kg/day)	Dermal MOE[b]	Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose[e] (mg/kg/day)	Dermal MOE[b]
Applicator Risk									
Applying Sprays with a Fixed-Wing Aircraft (3)	Pecans	No Data See Eng. Cont.	No Data See Eng. Cont.	No Data See Eng. Cont.	No Data See Eng. Cont.	No Data See Eng. Cont.	0.005	0.013	240
	Potatoes							0.016	190
	Sugar beets							0.021	140
Applying Sprays with a Groundboom Sprayer (4)	Potatoes	0.0066	460	0.011	0.0052	580	0.005	0.0023	1,300
	Sugar beets	0.0088	340		0.0069	440		0.003	960
Applying Sprays to Orchards with an Airblast Sprayer (5)	Pecans	0.09	33	0.22	0.055	55	0.019	0.0048	630
	Pecans (Typ)	0.06	50		0.037	82		0.0032	950
Mixer/Loader/Applicator Risk									
Mixing/Loading Liquids and Applying Sprays with a Groundboom Sprayer (6)	Potatoes	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.014	0.0064	470
	Sugar beets							0.0085	350
Mixing/Loading Liquids and Applying Sprays to Orchards with an Airblast Sprayer (7)	Pecans	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.028	0.0069	430
Mixing/Loading Wettable Powder (WSB) and Applying Sprays with a Groundboom Sprayer (8)	Potatoes	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.027	0.013	240
	Sugar beets							0.017	180
Mixing/Loading Wettable Powder (WSB) and Applying Sprays to Orchards with an Airblast Sprayer (9)	Pecans	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.041	0.010	290
Flagger Risk									
Flagging Spray Applications (10)	Pecans	0.024	120	0.01	0.022	140	0.00022	0.00048	6.,200
	Potatoes	0.012	250		0.011	270		0.00024	12,000
	Sugar beets	0.016	190		0.015	210		0.00032	9,400

Footnotes:

a Baseline Daily Dermal Dose (mg/kg/day) = Baseline Daily Dermal Exposure (mg/day)/Body weight (60 kg). Baseline dermal exposures are reported in Table 4.

Table 5. Occupational Short- and Intermediate-term Dermal MOEs for TPTH at Baseline and with Mitigation Measures (continued)

b Dermal MOE values calculated using the following equation: MOE = NOAEL (mg/kg/day)/Dermal Dose (mg/kg/day), where both short- and intermediate-term NOAEL = 3 mg/kg/day and an MOE of 100 is required. For private growers, only the short-term endpoint is applicable because exposures are not expected to exceed seven days.

c Additional PPE:

4, 5:	double layer clothing (Protection Factor = 50% for the second layer) with chemical-resistant gloves
10:	double layer clothing (Protection Factor = 50% for the second layer)

d Engineering Controls:

1a. 1b, 1c:	closed mixing system, single layer of clothing and chemical-resistant gloves	5:	enclosed cab, single layer clothing and chemical-resistant gloves
2a, 2b, 2c:	water soluble bags, double layer clothing, chemical-resistant gloves	6, 7:	closed mixing system, gloves, and enclosed cab
3:	enclosed cockpit, single layer clothing, and no gloves	8, 9:	water-soluble bags, gloves, and enclosed cab
4:	enclosed cab, single layer clothing, and no gloves	10:	enclosed truck (Protection Factor = 98%), single layer clothing, no gloves

e Daily Dermal Dose (mg/kg/day) = [(Unit Dermal Exposure (mg/lb ai) * Max. App. Rate (lb ai/A) * Max. Acres Treated) / Body Weight (60 kg)]

f There is no Unit Exposure for mixer/loader to add the applying unit exposure until engineering controls.

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Table 6. Occupational Inhalation MOEs for TPTH at Baseline and with Mitigation Measures

Exposure Scenario (Scen. #)	Crop Type or Target	Baseline Daily Inhalation Dose[a] (mg/kg/day)	Baseline Inhalation MOE[b]	Risk Mitigation Measures					
				Additional PPE[c]			Engineering Controls[d]		
				Unit Inhalation Exposure (µg/lb ai)	Daily Inhalation Dose[c] (mg/kg/day)	Inhalation MOE[b]	Unit Inhalation Exposure (µg/lb ai)	Daily Inhalation Dose[c] (mg/kg/day)	Inhalation MOE[b]
Mixer/Loader Risk									
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	Pecans	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	0.083	1.8E-04	520
	Potatoes							2.2E-04	410
	Sugar beets							3.0E-04	310
Mixing/Loading Liquids for Groundboom Application (1b)	Potatoes							3.3E-05	2,800
	Sugar beets							4.4E-05	2,100
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)	Pecans							1.8E-05	5,200
Mixing/Loading Wettable Powder (WSB) for Aerial/Chemigation Application (2a)	Pecans	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	0.071	1.5E-04	600
	Potatoes							1.9E-04	480
	Sugar beets							2.5E-04	360
Mixing/Loading Wettable Powder (WSB) for Groundboom Application (2b)	Potatoes							2.9E-05	3,200
	Sugar beets							3.8E-05	2,400
Mixing/Loading Wettable Powder (WSB) for Orchard Airblast Sprayer Application (2c)	Pecans							1.5E-05	6,000
Applicator Risk									
Applying Sprays with a Fixed-Wing Aircraft (3)	Pecans	No Data See Eng. Cont.	No Data See Eng. Cont.	No Data See Eng. Cont.	No Data See Eng. Cont.	No Data See Eng. Cont.	0.068	1.5E-04	630
	Potatoes							1.8E-04	510
	Sugar beets							2.4E-04	380
Applying Sprays with a Groundboom Sprayer (4)	Potatoes	0.0003	310	0.15	6.0E-05	1,500	0.043	1.7E-05	5,300
	Sugar beets	0.0004	230		8.0E-05	1,100		2.3E-05	4,000

Table 6. Occupational Inhalation MOEs for TPTH at Baseline and with Mitigation Measures (continued)

Exposure Scenario (Scen. #)	Crop Type or Target	Baseline Daily Inhalation Dose[a] (mg/kg/day)	Baseline Inhalation MOE[b]	Risk Mitigation Measures					
				Additional PPE[c]			Engineering Controls[d]		
				Unit Inhalation Exposure (µg/lb ai)	Daily Inhalation Dose[e] (mg/kg/day)	Inhalation MOE[b]	Unit Inhalation Exposure (µg/lb ai)	Daily Inhalation Dose[e] (mg/kg/day)	Inhalation MOE[b]
Applying Sprays to Orchards with an Airblast Sprayer (5)	Pecans	0.00096	95	0.9	1.9E-04	480	0.45	9.6E-05	950
	Pecans (Typ)	0.00064	140		1.3E-04	720		6.4E-05	1,400
Mixer/Loader/Applicator Risk									
Mixing/Loading Liquids and Applying Sprays with a Groundboom Sprayer (6)	Potatoes	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.13	5.1E-05	1,800
	Sugar beets							6.8E-05	1,400
Mixing/Loading Liquids and Applying Sprays to Orchards with an Airblast Sprayer (7)	Pecans	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.53	1.1E-04	810
Mixing/Loading Wettable Powder (WSB) and Applying Sprays with a Groundboom Sprayer (8)	Potatoes	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.11	4.6E-05	2,000
	Sugar beets							6.1E-05	1,500
Mixing/Loading Wettable Powder (WSB) and Applying Sprays to Orchards with an Airblast Sprayer (9)	Pecans	N/A[f]	N/A[f]	N/A[f]	N/A[f]	N/A[f]	0.52	1.1E-04	820
Flagger Risk									
Flagging Spray Applications (10)	Pecans	0.00066	140	0.07	1.3E-04	700	0.007	1.3E-05	7,000
	Potatoes	0.00033	280		6.6E-05	1,400		6.6E-05	14,000
	Sugar beets	0.00044	210		8.8E-05	1,100		8.8E-06	11,000

Footnotes:

a Baseline Daily Inhalation Dose (mg/kg/day) = Baseline Daily Inhalation Exposure (mg/day)/Body weight (70 kg). Baseline Inhalation exposures are reported in Table 4.

b Inhalation MOE values calculated using the following equation: MOE = NOAEL (mg/kg/day)/Inhalation Dose (mg/kg/day), where inhalation NOAEL = 0.092 mg/kg/day and an MOE of 100 is required

c Additional PPE:

4, 5, and 10: dust/mist respirator

d Engineering Controls:

1a. 1b, 1c: closed mixing system

2a, 2b, 2c: water soluble bags

3: enclosed cockpit

6, 7: closed mixing system and closed cab

8, 9: water-soluble bag and enclosed cab

10: enclosed truck (Protection Factor = 98%)

Table 7. Occupational Inhalation MOEs for TPTH at Baseline and with Mitigation Measures (continued)

4, 5: enclosed cab

e Daily Inhalation Dose (mg/kg/day) = [(Unit Inhalation Exposure (µg/lb ai) * (1 mg/1,000 µg) conversion factor * Max. App. Rate (lb ai/A) * Max. Acres Treated) / Body Weight (70 kg)]

f There is no Unit Exposure for mixer/loader to add the applying unit exposure until engineering controls.

The dermal and inhalation MOEs were calculated using the following formulas:

$$\text{Short-/ Intermediate-term Dermal MOE} = \frac{\text{Short-/ Intermediate-term Dermal NOAEL}\left(\frac{mg}{kg/day}\right)}{\text{Short-/ Intermediate-term Dermal Daily Dose}\left(\frac{mg}{kg/day}\right)}$$

$$\text{Inhalation MOE} = \frac{\text{Inhalation NOAEL}\left(\frac{mg}{kg/day}\right)}{\text{Inhalation Daily Dose}\left(\frac{mg}{kg/day}\right)}$$

For TPTH, the short- and intermediate-term dermal MOEs were calculated using a NOAEL of 3.0 mg/kg/day (from a rabbit dermal developmental study), and the inhalation MOE was calculated using a NOAEL of 0.092 mg/kg/day (from a rat inhalation study). The resulting dermal and inhalation MOEs were not combined because the endpoints were based on different effects (i.e., dermal - no observed effect at highest dose tested, and inhalation - death following lung lesions).

2.1.4 Handler Exposure and Risk Estimates for Cancer

Handler exposure assessments were completed by EPA using a baseline exposure scenario and increasing levels of risk mitigation (PPE and engineering controls) to achieve cancer risks of 1.0E-4 to 1.0E-6, or less. Tables 7, 8 and 9 present total cancer risk calculations at baseline, with PPE and with engineering controls, respectively, for each exposure scenario.

The calculations of daily dermal and inhalation exposure to TPTH by handlers were used to calculate the daily dose, and hence the risks, to those handlers. Potential daily dermal exposure was calculated using the following formula:

$$\text{Daily Dermal Exposure}\left(\frac{mg\ ai}{day}\right) = \text{Unit Exposure}\left(\frac{mg\ ai}{lb\ ai}\right) \times \text{Use Rate}\left(\frac{lb\ ai}{A}\right) \times \text{Daily Acres Treated}\left(\frac{A}{day}\right)$$

Potential daily inhalation exposure was calculated using the following formula:

$$\text{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) =$$
$$\text{Unit Exposure}\left(\frac{\mu g\ ai}{lb\ ai}\right) \times \text{Conversion Factor}\left(\frac{1mg}{1{,}000\ \mu g}\right) \times \text{Use Rate}\left(\frac{lb\ ai}{A}\right) \times \text{Daily Acres Treated}\left(\frac{A}{day}\right)$$

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Table 7. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH at Baseline

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e] (acres)	Baseline Daily Dermal Exposure[f] (mg/day)	Baseline Daily Inhalation Exposure[g] (mg/day)	Baseline Total Daily Dose (mg/kg/day)	Number of Exposures per Year[i]	Baseline LADD[j] (mg/kg/day)	Baseline Total Cancer Risk[k]
Mixer/Loader Exposure											
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	See Engineering Control	See Engineering Control	0.25	Pecans	400	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control
			0.125	Potatoes	1,000[l]						
			0.125	Sugar beets	1,000						
Mixing/Loading Liquids for Groundboom Application (1b)			0.125	Potatoes	150						
			0.125	Sugar beets	150						
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)			0.25	Pecans	40						
Mixing/Loading Wettable Powder (WSB) for Aerial/Chemigation Application (2a)	See Engineering Control	See Engineering Control	0.25	Pecans	400	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control
			0.125	Potatoes	1,000[l]						
			0.125	Sugar beets	1,000						
Mixing/Loading Wettable Powder (WSB) for Groundboom Application (2b)			0.125	Potatoes	150						
			0.125	Sugar beets	150						
Mixing/Loading Wettable Powder (WSB) for Orchard Airblast Sprayer Application (2c)			0.25	Pecans	40						
Applicator Exposure											
Applying Sprays with a Fixed-Wing Aircraft (3)	No Data See Eng. Cont.	No Data See Eng. Cont.	0.25	Pecans	400	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control
			0.125	Potatoes	1,000						
			0.125	Sugar beets	1,000						

Table 7. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH at Baseline (continued)

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e] (acres)	Baseline Daily Dermal Exposure[f] (mg/day)	Baseline Daily Inhalation Exposure[g] (mg/day)	Baseline Total Daily Dose (mg/kg/day)	Number of Exposures per Year[i]	Baseline LADD[j] (mg/kg/day)	Baseline Total Cancer Risk[k]
Applying Sprays with a Groundboom Sprayer (4)	0.014	0.74	0.125	Potatoes	150	0.26	0.014	0.00057	96 / 3	7.5E-5 / 2.4E-6	1.4E-4 / 4.3E-6
			0.125	Sugar beets	150	0.26	0.014	0.00057	58 / 3	4.6E-5 / 2.4E-6	8.3E-5 / 4.3E-6
Applying Sprays to Orchards with an Airblast Sprayer (5)	0.36	4.5	0.25	Pecans	40	3.6	0.045	0.0058	3	2.4E-5	4.4E-5
Mixer/Loader/Applicator Exposure											
Mixing/Loading Liquids and Applying Sprays with a Groundboom Sprayer (6)	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	0.125	Potatoes	150	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control
			0.125	Sugar	150						
Mixing/Loading Liquids and Applying Sprays to Orchards with an Airblast Sprayer (7)			0.25	Pecans	40						
Mixing/Loading Wettable Powder (WSB) and Applying Sprays with a Groundboom Sprayer (8)			0.125	Potatoes	150						
			0.125	Sugar	150						
Mixing/Loading Wettable Powder (WSB) and Applying Sprays to Orchards with an Airblast Sprayer (9)			0.25	Pecans	40						
Flagger Exposure											
Flagging Spray Applications (10)	0.011	0.35	0.25	Pecans	350	1.0	0.031	0.0018	1	2.5E-6	4.5E-6
			0.125	Potatoes	350	0.48	0.015	0.00091	15	1.9E-5	3.4E-5
			0.125	Sugar	350	0.48	0.015	0.00091	9	1.1E-5	2.0E-5

Footnotes:

a Baseline dermal unit exposure reflects long pants, long-sleeved shirt, no gloves, open mixing/loading, and open cab. Reference to engineering controls is made because TPTH is formulated only to be used with a closed mixing/loading system (liquid) or as a water-soluble bag (wettable powder).

b Baseline inhalation unit exposure reflects no respiratory protection. Reference to engineering controls is made because TPTH is formulated only to be used with a closed mixing/loading system (liquid) or as a water-soluble bag (wettable powder).

c Application rates: Unless otherwise stated, all rates are maximum rates and come from values found in the LUIS report and on TPTH labels. In cases where the maximum rate yields a risk that exceeds the level of concern (i.e., Cancer risk > 1E-4), calculations are also performed using the typical rate (indicated by "Typ") which comes from BEAD.

d Crop Type or Target provides a description of the intended uses of various products containing TPTH.

Table 7. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH at Baseline (continued)

For the following footnotes, in the cases where the "acres treated" or "number of exposures per year" are different for commercial applicator and private grower, both estimates are presented, separated by a "/" in the following manner: commercial value / private grower value.

e Amount Treated Per Day values are from BEAD.
f Baseline Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day).
g Baseline Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day)
h Baseline Total Daily Dose = [Baseline Daily Dermal Exposure (mg/day) * 0.1 (Dermal Absorption Factor) + Baseline Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).
l Number of Exposures Per Year is based on information from BEAD: [(Acres per farm / A treated per day) * Applications per year * Farms per application]. BEAD provided data for both private grower and commercial applicator; therefore, values are presented for both, where applicable, in the following format: commercial value / private grower value.
j Baseline LADD (mg/kg/day) = Baseline Total Daily Dose (mg/kg/day) * (Number of days exposure per year /365 days per year) * 35 years worked/70 year lifetime.
k Baseline Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = 1.83E+00 $(mg/kg/day)^{-1}$.
l An acreage of 350, rather than 1000, was used to calculate private grower risk from mixing/loading for chemigation. The acreage of 1000 is applicable for aerial (commercial) application only.

Table 8. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH with PPE

Exposure Scenario (Scen. #)	PPE Dermal Unit Exposure[a] (mg/lb ai)	PPE Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e] (acres)	PPE Daily Dermal Exposure[f] (mg/day)	PPE Daily Inhalation Exposure[g] (mg/day)	PPE Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	PPE LADD[j] (mg/kg/day)	PPE Total Cancer Risk[k]
Mixer/Loader Exposure											
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	See Engineering Control	See Engineering Control	0.25	Pecans	400	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control
			0.125	Potatoes	1,000[l]						
			0.125	Sugar beets	1,000						
Mixing/Loading Liquids for Groundboom Application (1b)			0.125	Potatoes	150						
			0.125	Sugar beets	150						
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)			0.25	Pecans	40						
Mixing/Loading Wettable Powder (WSB) for Aerial/Chemigation Application (2a)	See Engineering Control	See Engineering Control	0.25	Pecans	400	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control
			0.125	Potatoes	1,000[l]						
			0.125	Sugar beets	1,000						
Mixing/Loading Wettable Powder (WSB) for Groundboom Application (2b)			0.125	Potatoes	150						
			0.125	Sugar beets	150						
Mixing/Loading Wettable Powder (WSB) for Orchard Airblast Sprayer Application (2c)			0.25	Pecans	40						
Applicator Exposure											
Applying Sprays with a Fixed-Wing Aircraft (3)	No Data See Eng. Cont.	No Data See Eng. Cont.	0.25	Pecans	400	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control	See Engineering Control
			0.125	Potatoes	1,000						
			0.125	Sugar beets	1,000						

Exposure Scenario (Scen. #)	PPE Dermal Unit Exposure[a] (mg/lb ai)	PPE Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e] (acres)	PPE Daily Dermal Exposure[f] (mg/day)	PPE Daily Inhalation Exposure[g] (mg/day)	PPE Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	PPE LADD[j] (mg/kg/day)	PPE Total Cancer Risk[k]
Applying Sprays with a Groundboom Sprayer (4)	0.011	0.15	0.125	Potatoes	150	0.21	0.0028	0.00033	96 / 3	4.4E-5 / 1.4E-6	8.1E-5 / 2.5E-6
			0.125	Sugar beets	150	0.21	0.0028	0.00033	58 / 3	2.7E-5 / 1.4E-6	4.9E-5 / 2.5E-6
Applying Sprays to Orchards with an Airblast Sprayer (5)	0.22	0.9	0.25	Pecans	40	2.2	0.0090	0.0033	3	1.3E-5	2.5E-5

Table 8. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH with PPE (continued)

Exposure Scenario (Scen. #)	PPE Dermal Unit Exposure[a] (mg/lb ai)	PPE Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e] (acres)	PPE Daily Dermal Exposure[f] (mg/day)	PPE Daily Inhalation Exposure[g] (mg/day)	PPE Total Daily Dose (mg/kg/day)[h]	Number of Exposures per Year[i]	PPE LADD[j] (mg/kg/day)	PPE Total Cancer Risk[k]
Mixer/Loader/Applicator Exposure											
Mixing/Loading Liquids and Applying Sprays with a Groundboom Sprayer (6)	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	0.125	Potatoes	150	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control	Not applicable for mixer/loader until engineering control
			0.125	Sugar	150						
Mixing/Loading Liquids and Applying Sprays to Orchards with an Airblast Sprayer (7)			0.25	Pecans	40						
Mixing/Loading Wettable Powder (WSB) and Applying Sprays with a Groundboom Sprayer (8)			0.125	Potatoes	150						
			0.125	Sugar	150						
Mixing/Loading Wettable Powder (WSB) and Applying Sprays to Orchards with an Airblast Sprayer (9)			0.25	Pecans	40						
Flagger Exposure											
Flagging Spray Applications (10)	0.01	0.07	0.25	Pecans	350	0.88	0.0061	0.0013	1	1.8E-6	3.4E-6
			0.125	Potatoes	350	0.44	0.0031	0.00067	15	1.4E-5	2.5E-5
			0.125	Sugar beets	350	0.44	0.0031	0.00067	9	8.2E-6	1.5E-5

Footnotes:

a PPE dermal unit exposure reflects double layer of clothing and chemical-resistant gloves, open mixing/loading, and open cab. Reference to engineering controls is made because TPTH is formulated only to be used with a closed mixing/loading system (liquid) or as a water-soluble bag (wettable powder).

b PPE inhalation unit exposure reflects a dust/mist respirator. Reference to engineering controls is made because TPTH is formulated only to be used with a closed mixing/loading system (liquid) or as a water-soluble bag (wettable powder).

c Application rates: Unless otherwise stated, all rates are maximum rates and come from values found in the LUIS report and on TPTH labels. In cases where the maximum rate yields a risk that exceeds the level of concern (i.e., cancer risk > 1E-4), calculations are also performed using the typical rate (indicated by "Typ") which comes from BEAD.

d Crop Type or Target provides a description of the intended uses of various products containing TPTH.

For the following footnotes, in the cases where the "acres treated" or "number of exposures per year" are different for commercial applicator and private grower, both estimates are presented, separated by a "/" in the following manner: commercial value / private grower value.

e Amount Treated Per Day values are from BEAD.

f PPE Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day).

g PPE Daily Inhalation Exposure (mg/day) = Unit Exposure (μg/lb ai) * (1 mg/1000 μg) Conversion * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day)

h PPE Total Daily Dose = [PPE Daily Dermal Exposure (mg/day) * 0.1 (Dermal Absorption Factor) + PPE Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).

Table 8. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH with PPE (continued)

i Number of Exposures Per Year is based on information from BEAD: [(Acres per farm / A treated per day) * Applications per year * Farms per application]. BEAD provided data for both private grower and commercial applicator; therefore, values are presented for both, where applicable, in the following format: commercial value / private grower value.

j PPE LADD (mg/kg/day) = PPE Total Daily Dose (mg/kg/day) * (Number of days exposure per year /365 days per year) * 35 years worked/70 year lifetime.

k PPE Total Cancer Risk = PPE LADD (mg/kg/day) * (Q_1*), where Q_1* = 1.83E+00 $(mg/kg/day)^{-1}$.

l An acreage of 350, rather than 1000, was used to calculate private grower risk from mixing/loading for chemigation. The acreage of 1000 is applicable for aerial (commercial) application only.

Table 9. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH with Engineering Controls

Exposure Scenario (Scen. #)	Eng. Cont. Dermal Unit Exposure[a] (mg/lb ai)	Eng. Cont. Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e] (acres)	Eng. Cont. Daily Dermal Exposure[f] (mg/day)	Eng. Cont. Daily Inhalation Exposure[g] (mg/day)	Eng. Cont. Total Daily Dose (mg/kg/day)	Number of Exposures per Year[i]	Eng. Cont. LADD[j] (mg/kg/day)	Eng. Cont. Total Cancer Risk[k]
Mixer/Loader Exposure											
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	0.0086	0.083	0.25	Pecans	400	0.86	0.0083	1.3E-3	1	1.8E-6	3.4E-6
			0.125	Potatoes	1,000 / 350[l]	1.1 / 0.38[l]	0.010/ 0.0036[l]	1.7E-3 / 5.9E-4	15 / 1	3.5E-5 / 8.1E-7	6.3E-5 / 1.5E-6
			0.125	Sugar beets	1,000	1.1	0.010	1.7E-3	9	2.1E-5	3.8E-5
Mixing/Loading Liquids for Groundboom Application (1b)			0.125	Potatoes	150	0.16	0.0016	2.5E-4	96 / 3	3.3E-5 / 1.0E-6	6.1E-5 / 1.9E-6
			0.125	Sugar beets	150	0.16	0.0016	2.5E-4	58 / 3	2.0E-5 / 1.0E-6	3.7E-5 / 1.9E-6
Mixing/Loading Liquid for Orchard Airblast Sprayer Application (1c)			0.25	Pecans	40	0.086	0.00083	1.3E-4	3	5.5E-7	1.0E-6
Mixing/Loading Wettable Powder (WSB) for Aerial/Chemigation Application (2a)	0.022	0.071	0.25	Pecans	400	2.2	0.0071	3.2E-3	1	4.4E-6	8.1E-6
			0.125	Potatoes	1,000 / 350[l]	2.8 / 0.96[l]	0.0089 / 0.0031[l]	4.1E-3 / 1.4E-3	15 / 1	8.3E-5 / 1.9E-6	1.5E-4 / 3.6E-6
			0.125	Sugar beets	1,000	2.8	0.0089	4.1E-3	9	5.0E-5	9.1E-5
Mixing/Loading Wettable Powder (WSB) for Groundboom Application (2b)			0.125	Potatoes	150	0.41	0.0013	6.1E-4	96 / 3	8.0E-5 / 2.5E-6	1.5E-4 / 4.6E-6
			0.125	Sugar beets	150	0.41	0.0013	6.1E-4	58 / 3	4.8E-5 / 2.5E-6	8.8E-5 / 4.6E-6
Mixing/Loading Wettable Powder (WSB) for Orchard Airblast Sprayer Application (2c)			0.25	Pecans	40	0.22	0.00071	3.2E-4	3	1.3E-6	2.4E-6
Applicator Exposure											
Applying Sprays with a Fixed-Wing Aircraft (3)	0.005	0.068	0.25	Pecans	400	0.50	0.0068	8.1E-4	1	1.1E-6	2.0E-6
			0.125	Potatoes	1,000	0.63	0.0085	1.0E-3	15	2.1E-5	3.8E-5
			0.125	Sugar beets	1,000	0.63	0.0085	1.0E-3	9	1.3E-5	2.3E-5

Table 9. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH with Engineering Controls (continued)

Exposure Scenario (Scen. #)	Eng. Cont. Dermal Unit Exposure[a] (mg/lb ai)	Eng. Cont. Inhalation Unit Exposure[b] (μg/lb ai)	Application Rates[c] (lb ai/A)	Crop Type or Target[d]	Amount Treated per Day[e] (acres)	Eng. Cont. Daily Dermal Exposure[f] (mg/day)	Eng. Cont. Daily Inhalation Exposure[g] (mg/day)	Eng. Cont. Total Daily Dose (mg/kg/day)	Number of Exposures per Year[i]	Eng. Cont. LADD[j] (mg/kg/day)	Eng. Cont. Total Cancer Risk[k]
Applying Sprays with a Groundboom Sprayer (4)	0.005	0.043	0.125	Potatoes	150	0.094	0.00081	1.5E-4	96 / 3	1.9E-5 / 6.0E-7	3.5E-5 / 1.1E-6
			0.125	Sugar beets	150	0.094	0.00081	1.5E-4	58 / 3	1.2E-5 / 6.0E-7	2.1E-5 / 1.1E-6
Applying Sprays to Orchards with an Airblast Sprayer (5)	0.019	0.45	0.25	Pecans	40	0.19	0.0045	3.4E-4	3	1.4E-6	2.5E-6
Mixer/Loader/Applicator Exposure											
Mixing/Loading Liquids and Applying Sprays with a Groundboom Sprayer (6)	0.0136	0.126	0.125	Potatoes	150	0.26	0.0024	4.0E-4	3	1.6E-6	3.0E-6
			0.125	Sugar beets	150	0.26	0.0024	4.0E-4	3	1.6E-6	3.0E-6
Mixing/Loading Liquids and Applying Sprays to Orchards with an Airblast Sprayer (7)	0.0276	0.233	0.25	Pecans	40	0.28	0.0053	4.7E-4	3	1.9E-6	3.5E-6
Mixing/Loading Wettable Powder (WSB) and Applying Sprays with a Groundboom Sprayer (8)	0.027	0.114	0.125	Potatoes	150	0.51	0.0021	7.5E-4	3	3.1E-6	5.7E-6
			0.125	Sugar beets	150	0.51	0.0021	7.5E-4	3	3.1E-6	5.7E-6
Mixing/Loading Wettable Powder (WSB) and Applying Sprays to Orchards with an Airblast Sprayer (9)	0.041	0.521	0.25	Pecans	40	0.41	0.0052	6.6E-4	3	2.7E-6	5.0E-6
Flagger Exposure											
Flagging Spray Applications (10)	0.00022	0.007	0.25	Pecans	350	0.019	0.00061	3.6E-5	1	5.0E-8	9.1E-8
			0.125	Potatoes	350	0.010	0.00031	1.8E-5	15	3.7E-7	6.8E-7
			0.125	Sugar beets	350	0.010	0.00031	1.8E-5	9	2.2E-7	4.1E-7

Footnotes:

a Eng. Cont. dermal unit exposure reflects closed mixing/loading (gloves worn) or water-soluble bags, and closed cab or cockpit. The unit exposure for scenarios 2a, 2b, and 2c also reflect double layer clothing and chemical-resistant gloves.

b Eng. Cont. inhalation unit exposure reflects closed mixing/loading or water-soluble bags, and closed cab or cockpit.

c Application rates: Unless otherwise stated, all rates are maximum rates and come from values found in the LUIS report and on TPTH labels. In cases where the maximum rate yields a risk that exceeds the level of concern (i.e., cancer risk > 1E-4), calculations are also performed using the typical rate (indicated by "Typ") which comes from BEAD.

d Crop Type or Target provides a description of the intended uses of various products containing TPTH.

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Table 9. Occupational Combined Dermal and Inhalation Cancer Risk for TPTH with Engineering Controls (continued)

For the following footnotes, in the cases where the "acres treated" or "number of exposures per year" are different for commercial applicator and private grower, both estimates are presented, separated by a "/" in the following manner: commercial value / private grower value.

e Amount Treated Per Day values are from BEAD.
f Eng. Cont. Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day).
g Eng. Cont. Daily Inhalation Exposure (mg/day) = Unit Exposure (µg/lb ai) * (1 mg/1000 µg) Conversion * Application Rate (lb ai/A) * Amount Treated Per Day (acres/day)
h Eng. Cont. Total Daily Dose = [Eng. Cont. Daily Dermal Exposure (mg/day) * 0.1 (Dermal Absorption Factor) + Eng. Cont. Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).
I Number of Exposures Per Year is based on information from BEAD: [(Acres per farm / A treated per day) * Applications per year * Farms per application]. BEAD provided data for both commercial applicator and private grower; therefore, values are presented for both, where applicable, in the following format: commercial value / private grower value.
j Eng. Cont. LADD (mg/kg/day) = Eng. Cont. Total Daily Dose (mg/kg/day) * (Number of days exposure per year /365 days per year) * 35 years worked/70 year lifetime.
k Eng. Cont. Total Cancer Risk = Eng. Cont. LADD (mg/kg/day) * (Q_1*), where Q_1* = 1.83E+00 $(mg/kg/day)^{-1}$.
l An acreage of 350, rather than 1000, was used to calculate private grower risk from mixing/loading for chemigation. The acreage of 1000 is applicable for aerial (commercial) application only.

The daily dermal and inhalation doses were calculated using a 70 kg body weight using the following formulas:

$$\text{Daily Dermal Dose}\left(\frac{\text{mg ai}}{\text{Kg/Day}}\right) = \text{Daily Dermal Exposure}\left(\frac{\text{mg ai}}{\text{Day}}\right) \times \left(\frac{1}{\text{Body Weight (Kg)}}\right) \times 0.1 \text{ Dermal Absorption Factor}$$

$$\text{Daily Inhalation Dose}\left(\frac{\text{mg ai}}{\text{kg/day}}\right) = \text{Daily Inhalation Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) \times \left(\frac{1}{\text{Body Weight (kg)}}\right)$$

$$\text{Total Daily Dose} = \text{Daily Dermal Dose}\left(\frac{\text{mg}}{\text{kg/day}}\right) + \text{Daily Inhalation Dose}\left(\frac{\text{mg}}{\text{kg/day}}\right)$$

The lifetime average daily dose (LADD) was calculated using the following formula:

$$\text{LADD}\left(\frac{\text{mg}}{\text{kg/day}}\right) = \text{Daily Total Dose}\left(\frac{\text{mg}}{\text{kg/day}}\right) \times \left(\frac{\text{days worked}}{365 \text{ days per year}}\right) \times \left(\frac{35 \text{ years worked}}{70 \text{ year lifetime}}\right)$$

Total cancer risk was calculated using the following formula:

$$\text{Total Cancer Risk} = \text{LADD} \times Q1^*$$

where $Q_1^* = 1.83E+00 \text{ (mg/kg/day)}^{-1}$

The following assumptions and factors were used in order to complete this cancer risk assessment:

- The average body weight of 70 kg is used, representing a typical adult.
- Exposure time is assumed to be 8 hours per day. This represents a typical work day.
- Exposure duration is assumed to be 35 years. This represents a typical working lifetime.
- Lifetime is assumed to be 70 years.
- For calculating dose, dermal absorption is assumed to be 10 percent, and inhalation absorption is assumed to be 100 percent.[1] The doses were added together to represent total daily dose and combined with the oral Q_1^* to estimate cancer risk.

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- The Q_1^* used in the cancer assessment was 1.83E+00 mg/kg/day^{-1}.

- The exposure frequencies were based on information from BEAD: [(typical number of acres per farm / typical number of acres treated per day) * typical number of applications per year * number of farms to which an application is made]. BEAD provided data for both commercial applicator and private grower; therefore, calculations were performed for both, where applicable. The typical farm sizes were reported to be: 23 acres for pecans (83 acres is a high-end estimate); 143 acres for potatoes (417 acres is a high-end estimate); and 159 acres for sugar beets (334 acres is a high-end estimate). The number of farms typically treated by a commercial applicator were estimated to be: one farm for pecans; 40 farms for potatoes; and 27 farms for sugar beets.[4]

2.1.5 Summary of Risk Concerns for Handlers, Data Gaps, and Confidence in Risk Estimates

Handler Scenarios with Risk Concerns. The calculations of short- and intermediate-term dermal risk indicate that **dermal** MOEs are more than 100 at **baseline** for the all the assessed exposure scenarios **except** the following:

- (5) applying sprays to orchards with an airblast sprayer (both the maximum and typical application rates yielded MOEs of concern).

When **additional PPE** is used, the **dermal** MOEs are still less than 100 for this scenario.

Please note that **scenarios 1abc, 2abc, 3, 6, 7, 8, and 9 were not assessed until engineering controls** were introduced. This occurred for scenarios 1 and 2 because both types of formulations of TPTH have inherent engineering controls for mixing/loading (i.e., the flowable concentrate is to be used with a closed system, and the wettable powder is only available in water-soluble bags). Scenarios 6 through 9 are affected for the same reason; unit exposures are not applicable for the mixing/loading portion. For scenario 3, no data are available for open cockpit during aerial application.

The **engineering control** assessment indicated that the **dermal** MOEs are more than 100 for all scenarios **except** the following:

- (1a) mixing/loading liquids for aerial application to sugar beets (only the maximum application rate yielded an MOE of concern), and

- (2a) mixing/loading wettable in water-soluble bags for aerial/chemigation application (for all crops, both the maximum and typical application rates yielded MOEs of concern).

The calculations of inhalation risk indicate that **inhalation** MOEs are more than 100 at **baseline** for the all the assessed exposure scenarios **except** the following:

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- (5) applying sprays to orchards with an airblast sprayer (only the maximum application rate yielded an MOE of concern).

The calculations of inhalation risk indicate that **inhalation** MOE for scenario 5 (at the maximum application rate) is more than 100 with **additional PPE**. The **engineering control** assessment indicates that all **inhalation** MOEs are greater than 100 (including scenarios 1, 2, 3, 6, 7, 8, and 9 which were not assessed at baseline or with additional PPE, for the reasons stated previously).

The calculations indicate that **cancer risks at baseline** are **greater than the 1.0E-4** for the following scenario:

- (4) applying sprays with a groundboom sprayer to potatoes (only the commercial applicator has a risk that exceeds HED's level of concern).

The calculations indicate that **cancer risks at baseline** are **in the range of 1.0E-4 to 1.0E-6** for all of the other scenarios. With **addition of PPE**, the cancer risks for all of the scenarios are **in the range of 1.0E-4 to 1.0E-6**.

Please note that, as stated previously, **scenarios 1abc, 2abc, 3, 6, 7, 8, and 9 were not assessed until engineering controls** were introduced. This occurred for scenarios 1 and 2 because both types of formulations of TPTH have inherent engineering controls for mixing/loading (i.e., the flowable concentrate is to be used with a closed system and the wettable powder is only available in water-soluble bags). Scenarios 6 through 9 are affected for the same reason; unit exposures are not applicable for the mixing/loading portion. For scenario 3, no data are available for open cockpit during aerial application.

The calculations indicate that **cancer risks with Engineering Controls** are **greater than the 1.0E-4** for the following scenarios:

- (2a) mixing/loading wettable powder in water-soluble bags for aerial/chemigation application to potatoes (only the commercial applicators have risks that exceed HED's level of concern), and
- (2b) mixing/loading wettable powder in water-soluble bags for groundboom application to potatoes (only the commercial applicators have risks that exceed HED's level of concern).

The calculations indicate that **cancer risks with Engineering Controls** are **in the range of 1.0E-4 to 1.0E-6** for all of the other scenarios, except the flagging scenario, which has risks that are **less than 1.0E-6**.

Data Gaps. Chemical specific or PHED data do not exist for applying sprays with a fixed-wing aircraft with an open cockpit.

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Data Quality and Confidence in Assessment. Several issues must be considered when interpreting the occupational exposure risk assessment. These include the following:

- Surrogate PHED data were used to assess exposure for all but two of the major exposure scenarios (2abc - mixing/loading wettable powder in water-soluble bags, and 5 - applying sprays to orchards with an airblast sprayer). Surrogate PHED unit exposure values generally fall between the geometric mean and the median of the data set used to calculate the value.

- The design of the study for mixing/loading wettable powder in water-soluble bags resulted in a unit exposure that is not optimal for assessing exposures from handling large quantities of material. Only enough formulation to treat 5 acres was mixed/loaded for each study replicate, while the treatment area for groundboom and aerial application is 150 acres and 1000 acres, respectively.

- Several handler assessments were completed using "low quality" PHED data due to the lack of a more acceptable data set (see Table 3 for the specific scenarios where only "low quality" data were available).

- Several generic protection factors were used to calculate handler exposures. These protection factors are general estimates and variability may be significant.

- Factors used to calculate daily exposures to handlers (including acres treated per day) are based on researched information from BEAD, label directions, registrants' handouts from the SMART meeting, and professional judgement for the broad range of sites, equipment, and methods that are possible for each scenario.

2.2 Occupational Post-Application Exposures and Risks

2.2.1 Postapplication Exposure Scenarios

HED has determined that there are potential postapplication exposures to individuals entering treated areas for the purpose of:

- Harvesting pecans (although this is done mechanically, it is a very dusty operation);
- Scouting and moving hand-set irrigation pipes for potatoes and sugar beets; and
- Harvesting, sorting/packing, and brushing/washing potatoes and sugar beets. Although this is usually done mechanically for potatoes, there may be some farms at which these activities are performed by hand. For sugar beets, these activities are done almost exclusively by mechanical means and, therefore, will not be considered further. However, in the case that hand methods are used for sugar beet harvesting, the exposures are not expected to exceed those encountered during potato-harvesting activities.

None of these crop activities have been identified as scenarios yielding potential **chronic** exposure (i.e., ≥ 180 days of exposure/year) concern.

All the crops and activities likely to result in postapplication exposure from TPTH have been assessed for **cancer risk**.

2.2.2 Data Sources and Assumptions for Scenarios Considered

The following chemical-specific postapplication human reentry and transferable residue data were submitted in support of the reregistration of TPTH:

Human Reentry Data (MRID# 43557401)

The following is a summary of the review of this submission, as excerpted from "Revised Occupational Risk Assessment for the Use of TPTH on Pecans" (Lewis, P. and Scheltema, C., 1997).[6]

"The TPTH registrants submitted pecan reentry data based on monitoring pecan workers in Georgia and Texas for dermal and inhalation exposure (5 replicates for each route) while operating pecan windrowing equipment (Evans, 1996). TPTH was applied at 0.375 lb. ai/acre at both sites with the typical TPTH dilution of 100 gallons water/acre in Georgia and a minimum TPTH dilution of 20 gallons water/acre in Texas. Ten TPTH applications were made at each site. Airblast applications occurred during full season use in Georgia and Texas (Brennan and

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Leighton, 1996). Workers were monitored 70 and 71 days after the last TPTH application at the Georgia site and 43 and 44 days after application at the Texas site. Inhalation monitoring was conducted via personal air pumps connected to glass fiber filters. Soil and thatch samples were also collected from the dripline beneath treated pecan trees (Evans, 1996). Table 10 represents geometric means of the harvester monitoring data."

Table 10. Geometric Mean Exposure of Harvesters Reentering Pecan Groves Treated with TPTH

Body Region	Georgia (70-71 days post application) (µg/kg/hr)	Texas (43-44 days post application) (µg/kg/hr)	Both Sites (µg/kg/hr)
Whole body	0.318	0.879	0.529
Hands	0.202	0.057	0.108
Face and Neck	0.029	0.022	0.025
Total Dermal Exposure	0.549	0.958	0.662
Total Inhalation Exposure	0.006	0.006	0.006
Total Exposure	0.590	1.029	0.779

Transferable Residue Data (MRID# 42507801)

The following is a summary of the review of this submission, as excerpted from "Review of Reentry Data Submission to Support the Reregistration of Triphenyltin Hydroxide (TPTH)." (Evans, J., 1993).[9]

"The registrants presented two dissipation studies (accession # 261749) previously accepted by EPA (September, 1986). The studies consisted of foliar and soil dissipation data following applications of TPTH to potatoes and peanuts. Although the registrants are not supporting the reregistration on peanuts, OREB determined that the potato data support the reregistration of TPTH on sugar beets largely due to the similar application rates and cultural techniques."

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"The REIs proposed by the registrant for potatoes and sugar beets address postapplication exposure to treated soil at harvest (hand-harvesting potatoes) and treated foliage during crop maintenance activities (moving hand-set irrigation pipes)."

"TPTH did not appear to dissipate in the potato soil residue study (conducted in Holandale, MN)....[therefore, it is appropriate to use] the highest daily mean level (1.359 parts per billion TPTH) at one day post application [in conjunction with] a soil/dermal transfer coefficient of 3.9 ng/ppb/hr, taken from a study conducted by the Medical University of South Carolina for the Agency's Pesticide Hazard Assessment Project (Youth in Agriculture: Dermal and Respiratory Exposure Assessment of Juvenile Potato Harvesters, Aroostock County, Maine, August, 1982, NTIS# PB88-194469)."

"The foliar dissipation curve is (log Y = -0.0573X + -0.498), from the TPTH foliar dissipation study accepted by EPA in 1986 (Y = the dislodgeable foliar residue in $\mu g/cm^2$ and X = the number of days after the application)."

These data were used in conjunction with standard assumptions to determine potential risks for the previously mentioned representative scenarios.

Assumptions Used in Postapplication Exposure Calculations (Cancer and Non-Cancer Risks). The assumptions used in the calculations for occupational postapplication risks include the following items:

- Application rates used for the calculations were derived using the following strategy:

    -- Harvesting pecans = not applicable, study provides exposure values ($\mu g/kg/hr$), therefore the calculation using application rate is not necessary (incidentally, the application rate was 0.375 lb ai/acre)
    -- Harvesting and maintenance activities for potatoes (non-cancer) = 0.1875 lb ai/acre
    -- Maintenance activities for sugar beets (non-cancer) = 0.25 lb ai/acre
    -- Harvesting and maintenance activities for potatoes or sugar beets (cancer) = 0.125 lb ai/acre

- Transfer coefficients (T_c) are not necessary for pecan harvesting estimates because the study provides exposure values ($\mu g/kg/hr$). For potato harvesting, a soil/dermal transfer coefficient of 3.9 ng/ppb/hr was used, based on the "Youth in Agriculture" study mentioned previously. For maintenance activities associated with potatoes and sugar beets, the transfer coefficient was assumed to be 2,500 cm^2/hr.

- Daily exposure is assumed to occur for 8 hours per day.

- The average body weight of 60 kg is used in the non-cancer risk estimates (due to a developmental endpoint), while for cancer estimates, 70 kg is used, representing a typical adult.

- Exposure frequency is estimated to be 40 days/year for pecan harvesting, and 30 days/year for potato and sugar beet maintenance activities and harvesting.

- Exposure duration is assumed to be 35 years. This represents a typical working lifetime.

- Lifetime is assumed to be 70 years.

- Dermal absorption is assumed to be 10 percent for cancer estimates because the Q_1* is not based on a dermal study, as in the handler assessment.

- The Q1* used in the cancer assessment is 1.83E+00 mg/kg/day $^{-1}$.

2.2.3 Postapplication Exposure and Non-cancer Risk Estimates

For pecans, the postapplication risks from TPTH have been assessed using exposure data for 43 days after treatment in Texas and 70 days after treatment in Georgia, provided in the previously-mentioned study. Results of the pecan postapplication assessment are presented in Table 11. Pecans are typically harvested between 35 and 60 days after shuck split (i.e., after the last application, because TPTH may no longer be applied when the shuck starts to open), but may be harvested as early as 21 days after shuck split.[3, 6] Exposure samples were only collected for one day at each site, with the collection day in Georgia (day 70) outside the typical harvest interval mentioned above. Hence, for the purpose of determining a feasible reentry interval (REI), it was necessary to estimate exposures for additional days throughout the season, including early harvest (day 21) and the typical harvest interval (days 36 to 60). This estimation was performed by extrapolating sampled exposures to correspond with the days on which soil/thatch residue samples were collected at each site. The extrapolation was conducted by applying the ratio of soil/thatch residues (residue level measured on a particular day : residue level on the day the exposure samples were collected) to the value of the measured exposure, as shown in the following equation:

$$\begin{array}{c}\textit{Estimated Exposure}\\ \textit{for Day X}\\ (\mu g/kg/hr)\end{array} = \left(\frac{\textit{S/T Residue on Day X}}{\textit{S/T Residue on Day of Measured Exposure}}\right) * \begin{array}{c}\textit{Measured Exposure on}\\ \textit{Day 43 (TX), Day 70 (GA)}\\ (\mu g/kg/hr)\end{array}$$

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Because residues were not measured on the day the exposure samples were collected at the two sites, an average residue (computed from the residue level measurements that bracket the day the exposure samples were collected) was used to represent the actual residue level. The soil/thatch residues, ratios, extrapolated exposures and corresponding risks for both sites are presented in Table 12. Please note that the worker's exposure at the Georgia site was approximately half of the worker's exposure at the Texas site (0.55 and 0.96 µg/kg/hr, respectively), while the soil/thatch residue at the Georgia site was more than twice as high as that of the Texas site (10.8 and 4.1 µg/g, respectively). This may be evidence to suggest that exposure during pecan harvesting is more dependent on the amount of dust created from windrowing activities than TPTH residues in the soil/thatch.

The following equation was used to estimate both the dermal and inhalation doses. Although inhalation exposure is not usually expected during reentry for most scenarios, pecan harvesting is a very dusty operation; therefore, exposure data were collected and used in this assessment.

$$Daily\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Hourly\ Exposure\left(\frac{\mu g\ ai}{kg\text{-}hr}\right) \times cf\left(\frac{1\ mg}{1{,}000\mu g}\right) \times Hours\ Worked\left(\frac{8\ hr}{day}\right)$$

Both the dermal and inhalation MOEs were calculated using the following formula:

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

For potatoes and sugar beets, the postapplication risks associated with foliage contact (i.e., maintenance activities) have been assessed using foliar dissipation data. The dislodgeable foliar residue (DFR) was calculated using the application rate and an estimated 4 percent of the rate applied as initial dislodgeable residue, and an estimated 12 percent dissipation per day. The initial percent dislodgeable residue was calculated using the study application rate and the predicted residue on day zero based on the regression equation (i.e., log Y = -0.0573X + -0.498). The dissipation rate was determined using the DFRs calculated with the regression equation.

The equation used to calculate the daily DFRs is presented below:

$$DFR\left(\frac{\mu g}{cm^2}\right) = AR\left(\frac{lb\ ai}{A}\right) \times CF\left(\frac{\mu g/cm^2}{lb\ ai/A}\right) \times F \times (1 - DR)^t$$

Where:

AR = application rate

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CF = conversion factor is 11.2 ug/cm^2 per lb ai/acre
F = fraction retained on foliage (4 percent)
DR = daily dissipation rate (12 percent per day)
t = days after treatment

Table 11. Postapplication Exposures and Risks from TPTH During Pecan Harvesting

Site	Dermal Exposure[a] (µg/kg/hr)	Inhalation Exposure[a] (µg/kg/hr)	Dermal Dose[b] (mg/kg/day)	Inhalation Dose[b] (mg/kg/day)	S- & I-term Dermal MOE[c]	Inhalation MOE[c]	LADD[d] (mg/kg/day)	Cancer Risk[e]
Texas (43-44 days post application)	0.958	0.006	0.0077	4.8E-05	390	1,900	4.5E-05	8.2E-05
Georgia (70-71days post application)	0.549	0.006	0.0044	4.8E-05	680	1,900	2.7E-05	4.9E-05

a Exposure values from Table 10.

b Daily Dose = [Exposure (µg/kg/hr) * cf (1 mg/ 1,000 µg) * 8 hr worked/day]

c MOE = NOAEL (mg/kg/day)/Dose (mg/kg/day), where dermal NOAEL = 3.0 mg/kg/day and inhalation NOAEL = 0.092 mg/kg/day, and an MOE of 100 is required

d LADD (mg/kg/day) = {[(Dermal Dose (mg/kg/day) * 0.1 dermal absorption] + Inhalation Dose (mg/kg/day)} * (40 days exposure per year /365 days per year) * 35 years worked/70 year lifetime.

e Cancer Risk = LADD (mg/kg/day) * (Q_1*), where Q_1* = 1.83E+00 $(mg/kg/day)^{-1}$.

Table 12. Estimated Postapplication Exposures and Risks Based on Residue Ratios During Pecan Harvesting

DAT	Soil/Thatch Residue (ug/g)[a]	Residue Ratio[b]	Estimated Exposure Based on Ratio (µg/kg/hr)[c]		Dose (mg/kg/day)[d]		MOE[e]		LADD[f] (mg/kg/day)	Cancer Risk[g]
			Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation		
Georgia										
0	42.9	4.0	2.2	0.024	0.017	1.9E-04	170	480	1.1E-04	1.9E-04
1	23.3	2.2	1.2	0.013	0.0095	1.0E-04	320	890	5.8E-05	1.1E-04
3	27	2.5	1.4	0.015	0.011	1.2E-04	270	770	6.7E-05	1.2E-04
7	10.8	1.0	0.55	0.0060	0.0044	4.8E-05	680	1900	2.7E-05	4.9E-05
14	11.7	1.1	0.59	0.0065	0.0048	5.2E-05	630	1800	2.9E-05	5.3E-05
21	18	1.7	0.92	0.010	0.0073	8.0E-05	410	1200	4.4E-05	8.1E-05
30	18.4	1.7	0.94	0.010	0.0075	8.2E-05	400	1100	4.5E-05	8.3E-05
60	10.7	0.99	0.54	0.0059	0.0044	4.8E-05	690	1900	2.6E-05	4.8E-05
90	10.9	1.01	0.55	0.0061	0.0044	4.8E-05	680	1900	2.7E-05	4.9E-05
120	3.5	0.32	0.18	0.0019	0.0014	1.6E-05	2100	5900	8.7E-06	1.6E-05
Texas										
0	7.2	1.76	1.682	0.011	0.013	8.4E-05	220	1100	7.8E-05	1.4E-04
1	7.4	1.80	1.729	0.011	0.014	8.7E-05	220	1100	8.1E-05	1.5E-04
3	3.8	0.93	0.888	0.006	0.007	4.4E-05	420	2100	4.1E-05	7.6E-05
7	6.4	1.56	1.495	0.009	0.012	7.5E-05	250	1200	7.0E-05	1.3E-04
14	9.2	2.24	2.150	0.013	0.017	1.1E-04	170	850	1.0E-04	1.8E-04
21	6.2	1.51	1.449	0.009	0.012	7.3E-05	260	1300	6.7E-05	1.2E-04
30	4.2	1.02	0.981	0.006	0.008	4.9E-05	380	1900	4.6E-05	8.4E-05
60	4.0	0.98	0.935	0.006	0.007	4.7E-05	400	2000	4.4E-05	8.0E-05
90	3.1	0.76	0.724	0.005	0.006	3.6E-05	520	2500	3.4E-05	6.2E-05
120	4.8	1.17	1.122	0.007	0.009	5.6E-05	330	1600	5.2E-05	9.6E-05

a Soil/thatch residues from pecan harvester exposure study (MRID# 43557401).

b Residue ratios calculated by dividing the residue level on a given day by the residue level on the day exposure samples were collected (assumed to be 10.8 µg/g for GA and 4.1 µg/g for TX).

c Estimated Exposure = exposures from Table 11 multiplied by residue ratio.

d Daily Dose = [Estimated Exposure (µg/kg/hr) * cf (1 mg/ 1,000 µg) * 8 hr worked/day]

e MOE = NOAEL (mg/kg/day)/Dose (mg/kg/day), where dermal NOAEL = 3.0 mg/kg/day and inhalation NOAEL = 0.092 mg/kg/day, and an MOE of 100 is required

f LADD (mg/kg/day) = {[(Dermal Dose (mg/kg/day) * 0.1 dermal absorption] + Inhalation Dose (mg/kg/day)} * (40 days exposure per year /365 days per year) * 35 years worked/70 year lifetime.

g Cancer Risk = LADD (mg/kg/day) * (Q_1*), where Q_1* = 1.83E+00 $(mg/kg/day)^{-1}$.

Daily Doses for maintenance activities (foliar contact) were calculated as follows:

$$Dose\ (mg/kg/day) = \frac{DFR\ (\mu g/cm^2) \times Tc\ (cm^2/hr) \times CF\left(\frac{1\ mg}{1{,}000\ \mu g}\right) \times ED\ (hrs/day)}{BW\ (kg)}$$

Where:

DFR = daily DFR, as calculated above for the assumed average reentry day
Tc = transfer coefficient; 2,500 cm^2/hr for maintenance activities
CF = conversion factor (i.e., 1 mg/1,000 μg)
ED = exposure duration; 8 hours worked per day
BW = body weight (60 kg - developmental endpoint)

For soil contact associated with hand harvesting potatoes, the postapplication risks have been assessed using soil residue data. Because TPTH does not appear to dissipate in soil (no dissipation at the Minnesota site), the highest daily mean value of TPTH (1.329 ppb) at one day post application was used as the daily transferable residue on any given day.

Daily Doses for hand harvesting (soil contact) were calculated as follows:

$$Dose\ (mg/kg/day) = \frac{SR\ (ppb) \times Tc\ (ng/ppb/hr) \times CF\left(\frac{1\ mg}{1{,}000{,}000\ ng}\right) \times ED\ (hrs/day)}{BW\ (kg)}$$

Where:

SR = daily soil residue, 1.329 ppb
Tc = transfer coefficient; 3.9 ng/ppb/hr for hand harvesting activities
CF = conversion factor (i.e., 1 mg/1,000,000 ng)
ED = exposure duration; 8 hours worked per day
BW = body weight (60 kg - developmental endpoint)

MOEs were calculated as follows:

$$MOE = \frac{NOAEL\ (mg/kg/day)}{Dose\ (mg/kg/day)}$$

Where:

NOAEL = 3.0 mg/kg/day (short- and intermediate-term dermal)
Dose = calculated dermal dose

The calculated **MOE for hand harvesting (soil contact) is 4.3E+6** on any given day. Table 13 presents the MOEs for maintenance activities (foliar contact).

2.2.4 Postapplication Exposure and Risk Estimates for Cancer

The lifetime average daily dose (LADD) and cancer risks for pecan harvesting are presented in Table 11. The **LADD and cancer risk for hand harvesting (soil contact) potatoes are 2.4E-09 and 4.5E-09, respectively**, on any given day. The LADD and cancer risks for maintenance activities (foliage contact) are provided in Table 13.

The LADD and cancer risk for pecan harvesting was calculated using the following formula:

$$LADD = \frac{[(Dermal\ Dose * ABS) + Inhalation\ Dose] * EF * ED}{LT * 365\ days/yr}$$

Where:

Dose = calculated previously in non-cancer section (mg/kg/day)
ABS = absorption factor (0.1);
EF = exposure frequency (40 days/year)
ED = exposure duration (35 years for occupational risks)
LT = lifetime (70 years).

The LADDs for maintenance activities (foliage contact) and hand harvesting (soil contact) for potatoes and sugar beets were calculated using the following equation:

$$LADD = \frac{[Dermal\ Dose * cf\left(\frac{60\ kg}{70\ kg}\right) * ABS] * EF * ED}{LT * 365\ days/yr}$$

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Where:

Dose = calculated previously in non-cancer section for foliage (using DFR) and soil (using SR) (mg/kg/day)

cf = conversion factor (60 kg/70kg - body weight adjustment from developmental endpoint to cancer)

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Table 13. Postapplication Risks from TPTH During Maintenance Activities

DAT[b]	Potatoes Non-cancer[a] App. Rate: 0.1875 lb ai/A			Sugar beets Non-cancer[a] App. Rate: 0.25 lb ai/A			Potatoes and Sugar beets Cancer[a] App. Rate: 0.125 lb ai/A		
	DFR[c] (ug/cm2)	Dose[d] (mg/kg/day)	MOE[e]	DFR[c] (ug/cm2)	Dose[d] (mg/kg/day)	MOE[e]	DFR[c] (ug/cm2)	LADD[f] (mg/kg/day)	Cancer Risk[g]
0	0.084	0.028	100	0.112	0.037	80	0.056	6.6E-05	1.2E-04
1	0.074	0.025	120	0.099	0.033	91	0.049	5.8E-05	1.1E-04
2	0.065	0.022	140	0.087	0.029	100	0.043	5.1E-05	9.3E-05
3	0.057	0.019	160	0.076	0.025	120	0.038	4.5E-05	8.2E-05
4	0.050	0.017	180	0.067	0.022	130	0.034	3.9E-05	7.2E-05
5	0.044	0.015	200	0.059	0.020	150	0.030	3.5E-05	6.4E-05
6	0.039	0.013	230	0.052	0.017	170	0.026	3.1E-05	5.6E-05
7	0.034	0.011	260	0.046	0.015	200	0.023	2.7E-05	4.9E-05
8	0.030	0.010	300	0.040	0.013	220	0.020	2.4E-05	4.3E-05
9	0.027	0.0089	340	0.035	0.012	250	0.018	2.1E-05	3.8E-05
10	0.023	0.0078	380	0.031	0.010	290	0.016	1.8E-05	3.4E-05

a The maximum application rates (0.1875 lb ai/A and 0.25 lb ai/A) were used for non-cancer assessment of potatoes and sugar beets, respectively. The typical application rate (0.125 lb ai/A) for both potatoes and sugar beets was used to estimate cancer risk.

b Days after treatment with TPTH.

c Dislodgeable foliar residue. Based on regression equation from study (MRID# 42507801) and using application rate indicated above, initial DFR of 4%, and a dissipation rate of 12% per day.

d Daily Dose = [DFR (µg/cm²) * Tc (2,500 cm²/hr) * cf (1 mg/ 1,000 µg) * 8 hr worked/day]/Body Weight (60 kg for developmental endpoint).

e MOE = NOAEL (mg/kg/day)/Dose (mg/kg/day), where NOAEL = 3.0 mg/kg/day, and an MOE of 100 is required

f LADD (mg/kg/day) = [(Dose (mg/kg/day) * cf (60 / 70 - to adjust from developmental body weight) * 0.1 dermal absorption] * (30 days exposure per year /365 days per year) * (35 years worked/70 year lifetime).

g Cancer Risk = LADD (mg/kg/day) * (Q_1*), where Q_1* = 1.83E+00 (mg/kg/day)$^{-1}$.

ABS = absorption factor (0.1);
EF = exposure frequency (30 days/year)
ED = exposure duration (35 years for occupational risks)
LT = lifetime (70 years).

Cancer risks were calculated using the following formula:

$$RISK = LADD * Q_1^*$$

where, $Q_1^* = 1.83E+00\ (mg/kg/day)^{-1}$.

2.2.5 Summary of Postapplication Risk Concerns, Data Gaps, and Confidence in Estimates

Postapplication Scenarios with Risk Concerns. The results of the **non-cancer** pecan harvesting assessment indicate that MOEs are greater than 100 for the days on which exposure sampling took place (43 days after treatment in Texas, and 70 days after treatment in Georgia). On other days or pecan harvesting, where actual exposure data were not collected, the estimated exposures (based on ratios of soil/thatch residues) yielded MOEs greater than 100 as early as day zero after treatment. For hand harvesting (i.e., soil contact) potatoes and sugar beets, MOEs are greater than 100 at zero days after treatment. The non-cancer assessment of maintenance activities (i.e., foliar contact during moving of irrigation pipes or scouting) indicates that MOEs are greater than 100 at zero days after application for potatoes, and at two days after application for sugar beets. Please note that although MOEs are greater than 100 on day zero after application for most of the above scenarios, these MOEs are based on a dermal endpoint. TPTH has the potential to be a primary eye irritant (toxicity category I), thus invoking the worker protection standard **(WPS) default REI of 48 hours**. The 48-hour REI is consistent with the current label; entry prior to this requires PPE as outlined in the WPS.

The results of the **cancer** risk assessment indicate **risks greater than 1.0E-4** for the following crops and activities:

- Pecan harvesting through 21 days after treatment in Texas and through 3 days after treatment in Georgia, and
- Maintenance activities for potatoes and sugar beets until 2 days after treatment.

The results of the **cancer** risk assessment indicate **risks in the range of 1.0E-4 to 1.0E-6** for the following crops and activities:

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- Pecan harvesting after day 21 in Texas and day 3 in Georgia, and
- Maintenance activities for potatoes and sugar beets at 2 or more days after treatment.

The results of the **cancer** risk assessment indicate **risks below 1.0E-6** for the following scenario:

- Hand harvesting potatoes at zero days after application.

Data Gaps, Quality, and Confidence

The following data gaps or uncertainties are associated with this assessment:

- Chemical-specific exposure and transferable residue data were used to complete this assessment. Most of these data have undergone at least primary review and have been considered acceptable, however, the studies are several years old and may require a more recent evaluation to ensure that adjustments were made according to our current policies.

- Factors used to calculate postapplication risks (e.g., hours exposure per day or days worked) are based on best professional judgment due to lack of data specific to each crop/activity combination.

3.0 RESIDENTIAL AND OTHER NON-OCCUPATIONAL EXPOSURES AND RISKS

There are no residential or non-occupational uses for TPTH; therefore exposures are not likely, nor are postapplication exposures expected. There is potential for spray drift during aerial application, however, HED does not currently have an approved method of assessing this scenario. Incident data does not indicate that spray drift is a problem.

References

1) U.S. EPA 1998, Triphenyltin Hydroxide (TPTH) Report of the Hazard Identification Assessment Review Committee, dated November 13, 1998.

2) U.S. EPA 1998. TPTH LUIS Table for Exposure Assessors (PRD report dated 3/09/98 and report run date 3/27/98.

3) TPTH Labels.

4) Internal EPA Memorandum from Chand-Goyal, T. and Keitt, G. of BEAD to Keigwin, T. and Doyle, E. of HED "Use Data for Exposure Analysis of TPTH: Additional Information II" September 9, 1998.

5) Registrants' (Griffin, AgrEvo, and Landis) handouts from the TPTH SMART Meeting, October 28, 1998.

6) Internal EPA Memorandum from Lewis, P. and Scheltema, C. of HED to Andreason, J. of SRRD "Revised Occupational Risk Assessment for the Use of TPTH on Pecans" March 6, 1997.

7) Exposure Science Advisory Council Policy Number 7: Use of Values from the PHED Surrogate Exposure Guide and from Analyses of Individual PHED Data Sets. January 28, 1999.

8) Pesticide Handler Exposure Database Version 1.1, Surrogate Exposure Guide. Health Effects Division, Office of Pesticide Programs, August, 1998.

9) Internal EPA Memorandum from Evans, J. of HED to Feris, E. of SRRD "Review of Reentry Data Submission to Support the Reregistration of Triphenyltin Hydroxide (TPTH)" March 1, 1993.

cc: K. O'Rourke, RAB III, 7509C
Loan Phan, SRRD, 7508C
Chemical File 083601

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