424338-11

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MEMORANDUM

TO: Al Nielsen EPA/OPP/OREB

cc: 2110.003 File
Tim Leighton
Jeff Evans

FROM: Jeff Dawson

DATE: 8/ /93

SUBJECT: Summary Review of "A Golfer Exposure Study With Chlorothalonil Used For Golf Course Maintenance - 1985" (MRID 424338-11)

A study was submitted in support of the registration requirements for the fungicide chlorothalonil formulated as Daconil 2787 Flowable Fungicide, a liquid formualtion containing 4.17 pounds active ingredient per gallon (40.4% by weight). These requirements were specified by the U.S. Environmental Protection Agency, herein referred to as the Agency, under Subdivision K (Exposure: Reentry Protection) of the Pesticide Assessment Guidelines (U.S. EPA, 1984 & U.S. EPA, 1988).

The following information can be used to identify the study:

Title:	A Golfer Exposure Study With Chlorothalonil Used For Golf Course Maintenance - 1985
Sponsor/Performing Laboratory:	Fermenta Plant Protection Company (SDS Biotech Corporation) 5966 Heisley Road P.O. Box 8000 Mentor, Ohio 44077
Critical Personnel:	D.L. Ballee: Study Director A.F. Marks: Mgr. Env. Services R.A. Baxter: V.P. Service Technology
Critical Dates:	Report Date: 12/10/90 Field Phase: 8/20/85-9/17/85 Analytical Termination: 1/28/86
Identifying Codes:	EPA MRID 424338-11 SDS Report No.: SDS-2787 SDS Doc. No.: 1148-85-0059-HE-001

Chlorothalonil is a broad spectrum fungicide used in a variety of agricultural, turf and forestry scenarios. "The objective of this study was to assess the potential exposure of typical golfers to chlorothalonil from playing golf on courses that had recieved label applications of Daconil 2787 Flowable Fungicide in normal maintenance programs through (1) measuring airborne concentration of chlorothalonil in the breathing zone and (2) measuring chlorothalonil on gloves, socks, and patches attached to both the outside and inside of clothing worn by each player."

The field phase of this study was conducted on two golf courses located in northeastern Ohio. The first was the Deer Lake Golf Club located in Geneva, Ohio while the second was the Quail Hollow Inn Golf Course located in Painesville, Ohio. All monitoring was performed at the Deer Lake course August 20, 1985 while all monitoring was completed at the Quail Hollow course September 17, 1985. [Note: This study was conducted in conjunction with the mixer, applicator, mower study for chlorothalonil (EPA MRID 424338-10) which is reviewed in a separate memo -- in that study there were a series of 3 Daconil applications each of the study sites.] "The golf players were monitored during their play of a round of golf on the day of the second weekly application of the test material. The golf players started as the application was being made just a few greens or fairways ahead of them as was typical on the golf courses on which this study was conducted. Application of the test material was made to all greens and fairways on the same day. These two factors (spraying greens and fairways on the same day plus playing following the sprayer) when combined created the potential for maximum possible exposure to chlorothalonil for golfers playing on golf courses that are normally treated with chlorothalonil formulations. The length of the monitoring period for both dermal and inhalation exposure was the time required individually by each player to complete the 18 hole golf course on each specific day. The time of exposure was recorded for each player for each day of the study. Each day for each player was designated a replicate. Three replicates were used for evaluating the effect on potential exposure from walking and three replicates for evaluating the effect from riding golf carts on each of the two courses." To summarize, the monitoring regimen for this study included a total of 12 replicates, 6 for walking golfers and 6 for golfers on carts.

"Daconil 2787 Flowable Fungicide was applied to the golf courses as part of an applicator exposure study, reported in document 1148-85-0051-HE-001 [study reviewed under separate cover/MRID 424338-10]." The following is a description of the application regimen for the mixer/applicator/mower study excerpted from the review memo for the same document. [Note: A series of three applications was completed for the mixer/applicator/mower study. However, golfer exposure was monitored after only the first and second of these applications.]

> *Applications of Daconil 2787 were made "with mounted sprayers at rates common to the normal usage pattern on these two golf courses [Deer Lake and Quail Hollow] ." The equipment used to make the applications at both study sites is summarized in the table below.*

Application Equipment Summary

Description	*Deer Lake Greens & Fairways*	*Quail Hollow Greens*	*Quail Hollow Fairways*
Manufacturer:	*Broyhill*	*Broyhill*	*F.E. Myers #7510*
Tank Capacity (Gal):	*120*	*150*	*200*
Pump Type:	*Centrifugal*	*Centrifugal*	*High Pressure Piston*
Pump Pressure (psi):	*40*	*35-40*	*120*
Spray Boom:	*24', 17 nozzles at 18" spacing*	*20', 13 nozzles at 20" spacing*	*No Data*
Nozzle Type:	*T Jet Flat Fan #8004*	*T Jet Flat Fan #8004*	*Broadcast Cluster, 3x0520 HE & 2xAOC20 nozzles*
Vehicle:	*Cushman Truckster*	*No Data*	*No Data*

The application rate for Daconil 2787 differed depending upon whether or not the treatments were made to the green or the fairway. The nominal application rate on greens was "4 oz per 1000 ft^2" while the rate on the fairways was "6 pints per acre" (i.e., greens: 3.12 lb ai/acre and fairways: 5.67 lb ai/acre). Actual application rates were, however, reported for each study site. "The greens applicator at Deer Lake applied Daconil 2787 Flowable Fungicide at an average rate of 3.85 oz/1000 ft^2 diluted in water to yield an average of 1.85 gallons of spray per 1000 ft^2. The greens applicator at Quail Hollow applied Daconil 2787 Flowable Fungicide at an application rate of 7.51 oz/1000 ft^2 diluted in an average of 2 gallons of spray preparation per 1000 ft^2. The fairways applicator at Deer Lake applied Daconil 2787 Flowable Fungicide at a mean rate of 5.83 pints/acre diluted in water to give an average of 18.4 gallons of spray preparation per acre. The fairways applicator at Quail Hollow applied Daconil at a mean rate of 5.97 pints/acre diluted in water to give an average of 29.7 gallons of spray/acre." Additionally, the area treated during each replicate differed throughout the study hence, the amount of chlorothalonil used differed for each replicate. In fact, "the mixer at Deer Lake utilized approximately 207 to 253 pints of Daconil 2787 Flowable Fungicide on each of the three days of preparation. This was equivalent to approximately 108 to 132 pounds of active ingredient for each day. The mixer at Quail Hollow utilized from approximately 182 to 222 pints of Daconil Flowable Fungicide on each of the three days of preparation or approximately 95 pounds to 116 pounds of active ingredient for each day." Finally, the the greens applicator at Deer Lake treated a total of approximately 5.4 acres while the

greens applicator treated a total of approximately 9.0 acres. The fairways applicator at Deer Lake treated approximately 106.1 acres while the fairways applicator at Quail Hollow treated approximately 58.4 acres.

Climatological data including "weather condition, temperature, relative humidity, barometric pressure, wind speed, and wind direction were taken several times during each day." These data were collected/determined using the same standard equipment at both sites (i.e., Qualimetrics Models #5011, #1548, & #2133 and a common tapered rain gauge). At Deer Lake during all operations, temperatures ranged from 68°F to 71°F with concurrent humidity levels ranging from 61% to 73%. At Quail Hollow during all operations, temperatures ranged from 53°F to 75°F with concurrent humidity levels ranging from 38% to 81%.

According to the study report, "each player wore a shirt with long sleeves and ankle length trousers. To this clothing were attached patches for evaluation of potential dermal exposure. Each patch was constructed as follows in sequence from base - a piece of denim, 2 layers of extra heavy duty aluminum foil, a 3 1/4" x 3 1/4" 12 ply gauze patch." All patches were attached to both the interiors and exteriors of the clothing worn by the test subjects. "The patches remained on for the entire monitoring period. Potential hand exposure was evaluated by the wearing of light cotton gloves by the player. The golfers wore a typical golf glove on the left hand (as all glofers in this study were right handed) over the light cotton glove. Only the light cotton gloves were collected. Potential head exposure was evaluated by the wearing of light cotton socks under the normally worn sock of the player. The normally worn outer sock was also collected. The sock was divided into an upper and lower portion using the upper limit of the shoe as the dividing line."

The following body areas were sampled for all players:

- Head - patch outside cap - front
- Chest - patches inside and outside shirt
- Back -- patches inside and outside shirt
- Shoulder -- patches outside shirt (right and left)
- Upper Arm -- patches outside (right and left)
- Forearm -- patches outside shirt (right and left)
  patches inside on sweatbands (right and left)
- Hand -- cotton gloves (right and left)
- Thigh -- patches outside trousers (right and left)
- Ankle -- patches inside and outside trousers (right and left)

- Foot -- inside sock (right and left)
- Foot -- outer sock (right and left) (upper and lower)
- Leg -- patches inside on sweatbands - below knee (right and left)"

Little description was provided in the study report regarding the inhalation monitoring regimen. However, the following was excerpted from the study report and protocol. "A tandem collecting system consisting of a filter cassette, followed by a sorbent tube will be placed as close as possible to the breathing zone of each player sampled. Air will be drawn through the collection system by a portable sampling pump attached to the player. In practice, the portable sampling pump will be attached to the belt of the slacks with the connection tube coming up over the player's shoulder. The open end of the collection system will be fastened to the collar or front of the shirt in the proximity of the breathing zone. The monitoring equipment will include:

- Filter Cassette - Consists of 37 mm 0.8 micron mixed cellulose acetate membrane filter (Millipore AAWP 03700), a support pad (Millipore AP 10037 x) and a two piece cassette (Millipore MO 00037 A0).
- Sorbent Tube - Chromsorb 102 (SKC, Inc. Tube # 226-49-23-102.
- Pumps - P-4000 or P-2500 Series of Constant Flow Rate Pumps (DuPont Co. # 2655 or 2652).
- Pump Flow Rate - Approximately 2.0 Liters per minute. Pump flow rates will be calibrated prior to the start of sampling and at the completion of the sampling period. The standard bubble tube flow technique method will be used for calibration purposes."

"At the end of each day all collected samples were transported to the Ricerca, Inc. site (less than 40 minutes from golf courses) [a subsidiary of SDS Biotech] where they were placed in frozen storage at temperatures not exceeding 0°C until time of assay." The report indicated that "all field samples were colected and identified in the field as per the protocol." The protocol indicated that the gauze patch samples were wrapped in aluminum foil then placed in "Ziploc plastic bags" for storage. Additionally, the protocol indicated that the "gloves and socks will be collected and handled as field samples. If more than one glove per hand is collected, all gloves per hand per player will be placed in the same sample bag." Finally, the protocol indicated "each filter cassette will be separated from the collecting device and both ends plugged with red or blue plastic plugs" followed by storage in "Ziploc" bags. "Each sorbent tube will be removed from the collection device and both ends plugged with red plastic caps" followed by storage in "Ziploc" bags.

According to the protocol, "the analytical portion of this study will be [was] conducted at the SDS Biotech Corporation, 7528 Auburn Road, Painesville, Ohio 44077." Additionally, the summary provided in the study report indicated that "chlorothalonil was extracted from the gauze patches, gloves (work and inner), socks (upper, lower, and inner), air filters and adsorbent tubes into toluene. The samples were shaken with toluene for a miniumum of one hour. All residues were quantified in toluene solution, after appropriate dilution, by electron capture gas chromatography." In addition to the procedures documented in the protocol the report indicated that "the aluminum foil wrapper placed around the gloves, socks and patches in the field was placed in the extraction jar with the sample." Operating conditions for the gas chromatograph are summarized in the table below.

Gas Chromatograph Operating Parameters

Instrument:	Varian GC equipped with ECD (^{63}Ni Detector)
Column:	3-5% OV-210 on 80/100 mesh Supelcoport 6' x 1/4" o.d. x 2 mm i.d./glass
Operating Temperatures (°C):	Oven: 160 to 190 Injector: 220 to 280 Detector: 330 to 350
Carrier Gas:	N_2 (UHP) at flows of 30 to 50 mL/min.

The analytical procedures used in this study were to have been validated "prior to initiation of and during sample assay" for each sample matrix. "Fortification levels covered the range of analytical values determined from the assay of study samples. The amended samples were processed through the described analytical procdure to evaluate its validity." In addition, extensive pre-field phase validation data were provided for the inhalation monitoring regimen. Two (2) distinct types of samples were generated and analyzed in order to validate the inhalation monitoring technique including: (1) desorption efficiency -- "spiking known amounts of chlorothalonil onto the adsorbents in the front section of the collection tubes and then drawing air through the tubes with the personal sampling pumps to simulate field sampling, and (2) collection efficiency -- a series of 2 experiments that involved depositing a known amount of chlorothalonil into empty glass tubes and drawing air (i.e., 2 flow rates/intervals were tested: 1.6 Lpm for @ 8 hrs. & 2.1 to 2.5 Lpm for @ 5 hrs.) through adsorbents placed in proximity to those tubes to capture airborne chlorothalonil residues. Finally, according to the report, because it was necessary to freeze samples after the field phase of the study until analysis "the effect of storage under frozen conditions upon the residue of chlorothalonil on air tubes, air filters, gauze pads, gloves and socks was evaluated." The results of these experiments were included as an appendix to the study report (i.e., SDS Biotech documents 655-3MD-84-0024-001-001 & 02 along with 4/10/86 memo). The results for these storage stability studies are presented and reviewed in a separate memo as they applicable to several of the studies submitted in support of chlorothalonil currently being reviewed by the Agency. All available quality control data included in this study are summarized below except for the storage stability results. All field sample analyses were

completed by January 28, 1986 -- @ 5 1/2 months after the initiation of the field phase of the study.

Analytical Method Validation/Recovery Data

Sample Matrix	Fortification Level Range (ug/sample)	N	Recovery (%) Mean	Std. Dev.
Chromsorb Tubes[1]	0.08 - 0.16	4	105.5	4.20
Chromsorb Tubes[2]	0.40 - 0.80	13	91.3	12.41
Chromsorb Tubes[3]	0.04 - 1.60	3	102.3	7.09
Chromsorb Tubes[4]	0.40 - 1.60	18	80.8	22.51
Chromsorb Tubes[5]	0.018 - 0.035	4	89.3	4.65
Gauze Patches[6]	3.40 - 100.0	24	96.0	6.53
Cotton Glove Dosimeters	20.0 - 5000.0	4	97.5	10.34
Outer Upper Socks	20.0 - 200.0	3	92.0	5.57
Outer Lower Socks	16.0 - 200.0	4	104.3	6.99
Inner Socks	16.0 - 200.0	4	97.0	12.57
Cellulose Filters	0.018 - 10.0	4	85.5	6.24

Notes:

(1) Pre-field phase desorption efficiency samples for adsorbent tube validation.

(2) Pre-field phase collection efficiency samples for adsorbent tube validation at a flow rate of 1.6 Lpm -- data generated during analytical validation for tomato re-entry study.

(3) Concurrent laboratory recovery samples for second collection efficiency study.

(4) Second pre-field phase collection efficiency study for adsorbent tube validation. Study conducted at flow rates of 2.1 to 2.5 Lpm over @ 4 to 5 hour intervals.

(5) Remaining recovery samples for adsorbent tube validation.

(6) Sample surface area of 68.15 cm^2 per patch. Therefore, the fortification range on a unit area basis is 0.050 - 1.467 ug/cm^2.

Detection limits (LOD) and quantitation limits (QL) for each sample matrix are presented in the table below. Target "non-detect" values as reported in the study protocol by the investigators are included below as the LOD. No quantitation limits, per se, were identified in the report. The values presented below as QL values were defined as the lowest fortification level for which adequate recovery was demonstrated for each sample matrix.

Detection/Quantitation Limit Summary

Sample Matrix	Quantitation Limit	Detection Limit
Chromsorb Tubes	0.018 ug/sample	0.05 ug/m^3
Cellulose Filters	0.018 ug/sample	0.05 ug/m^3
Gauze Patches	3.40 ug/sample or 0.050 ug/cm^2	0.05 ug/cm^2
All Gloves	20.00 ug/sample	0.05 ug/cm^2
Outer Upper Sock Sections	20.00 ug/sample	0.05 ug/cm^2
All Socks (except "Outer Upper" samples)	16.00 ug/sample	0.05 ug/cm^2

Exposure levels were presented in the study report along with a summary of the activities of the individual test subjects. The investigators presented the following summary exposure levels in the study report.

In addition to the data and analysis thereof presented in the report by the investigators, Versar prepared an analysis of the study results. This analysis includes a correlation of dermal/total exposure levels to various study parameters (e.g., chemical handled or area mowed).

Compliance with Subdivision K of the Pesticide Assessment Guidelines (U.S. EPA, 1984/U.S. EPA, 1988) is critical if this study is to be considered acceptable for regulatory purposes. The itemized lists below describe compliance with the major technical aspects of Subdivision K. The lists are based on the "Checklist for Post-Application Human Exposure Data" and the "Checklist for Residue Dissipation Data" used for study reviews by the U.S. EPA/OPP/ORFB. The individual checklists have been combined wherever appropriate and/or redundant.

Combined Lists:

- *Typical end-use product of the active ingredient used.* This criterion was met as Daconil 2787 Flowable Fungicide, a liquid flowable formulation containing 4.17 lb/gallon of the broad spectrum fungicide chlorothalonil (40.4% a.i.) was used to make all applications in the study.

- *Site(s) tested representative of reasonable worst-case climatic conditions expected in intended use areas.* This criterion was not met. The study was conducted in northeastern Ohio which is typically not considered a "worst-case" scenario for climatic conditions. Golf course cultural practices, for the most part, are similar in all geographic regions. However, average cliamtic conditions vary extensively within those same geographic regions (e.g., arid conditions such as California or Arizona and humid conditions such as Florida). As a result, more information needs to be provided regarding the environmental fate characteristics of chlorothalonil to clearly define adherence to this guideline requirement (e.g., if chlorothalonil is photolabile or hydrolabile).

- *End-use product applied by application method recommended for the crop. Application rate given and should be at the least dilution and highest, label permitted, application rate.* This criterion was partially met. The types of equipment used to treat both the greens and fairways were typical of equipment used for those scenarios and the unit spray volumes were acceptable per the label guidelines. However, the application rates used in the study were not acceptable and other types of equipment/exposure scenarios were allowable per the label that were not addressed in the study. In fact, the report indicated that "rates common to the normal usage pattern on these two golf courses [Deer Lake & Quail Hollow]" were used in the study. The maximum application rate for fairways and greens were 24 pt/acre and 11 oz/acre, respectively. The actual application rates in this study did not even approximate those rates at both of the study sites for any scenario (i.e., fairways: 5.83 and 5.97 pt/acre and greens: 3.85 and 7.51 oz/1000 ft^2 at Deer Lake and Quail Hollow, respectively). Additionally, the treatment of ornamentals (no high pressure equipment) and conifers (ground equipment, i.e., airblast) were both allowable per the label. Each of these scenarios have been shown, historically, to have significant exposures associated with them (e.g., based on PHED analysis). As a result, these scenarios/equipment types must be adequately addressed in any exposure assessment based on the complete spectrum of Daconil 2787 uses.

- *Application(s) occurred at time of season that the end-use product is normally applied to achieve intended pest control.* This criterion was not met. No information was presented in the report regarding the standard cultural practices associated with chlorothalonil use and golf course management.

- *Meteorological conditions including temperature, wind speed, daily rainfall and humidity provided for the duration of the study.* This criterion was partially met.

All required data were presented. However, irrigation is a common practice at most golf courses almost on a daily basis. Information needs to be provided regarding whether or not the treated areas were irrigated prior to the mowing component of the exposure monitoring regimen. Irrigation can significantly impact post-application residue levels and therefore the related exposure levels.

- *Residue storage stability, method efficiency (residue recovery), and limit of quantitation provided.* This criterion was not met. Storage stability data were generated for several chlorothalonil exposure studies concurrently using the same sample matrices. As a result, even though the storage stability data were included in this study, they will be evaluated in a separate memo which will include an analysis of the impact of the storage data on the results of this study. In addition to the storage stability study data described above one other factor must be considered. The report indicated that "at the end of each day all collected samples were transported to the Ricerca, Inc. site (less than 40 minutes from golf courses) where they were placed in frozen storage at temperatures not exceeding 0°C until time of assay." No information was provided in the report concerning the interim storage facilities (i.e., in the field) or the conditions the samples were subjected to before being placed in freezer storage. Additionally, recovery data were provided. However, the origin of the data was not explained in the report (i.e., it could not be determined if the samples were actually generated and analyzed concurrently with the field samples). It also appears that no field recovery samples were generated in this study. In fact, the protocol did not even require that these types of samples be generated/collected. Adequate pre-field analytical validation data were also not provided with the exception of data generated in support of the inhalation monitoring regimen. Finally, it could not definitively be determined if the quantitation/detection limits for all matrices were adequately sensitive because a large number of the field samples did not contain detectable chlorothalonil residues. The techniques used by the investigators to define these limits (i.e., QL/LOD) were also not reported (e.g., the investigators could have defined a quantitation limit based on the available QA/QC data and the LOD based on the GC detector response limit).

- *Concurrent foliar dislodgeable and/or soil residue dissipation data collected per Subdivision K, Section 132 Guidance.* This criterion was not met. Concurrent FDR and human re-entry/exposure data were not generated in this study.

- *Reported residue dissipation data in conjunction with toxicity data must be sufficient to support the determination of a reentry interval.* This criterion was not met. No toxicity or foliar dislodgeable residue dissipation data were generated/presented in this study.

Human Exposure Data:

- *Dermal and/or inhalation exposure monitored by validated methodologies (i.e., patches, whole-body dosimeters, personal air samplers).* This criterion was partially met. The exposure monitoring techniques used in this study by the investigators were classical in nature (i.e., Durham and Wolfe type patches, gloves and personal sampling pumps equipped with particulate filters and vapor adsorbing resin tubes -- no biological monitoring was conducted). However, the analytical quality control regimen in this study is inadequate (e.g., available data not clearly identified and no field recovery data generated). As a result, none of the sampling/monitoring technologies were validated from an analytical perspective in an acceptable manner (i.e., inadequate pre-field validation, no field phase validation and the techniques for generating available samples/data were not described).

- *Study participant activity contributing to exposure should be consistent with typical accepted agricultural practices.* This criterion was not met. No adequate discussion of the typical commercial practices pertaining to the use of chlorothalonil on golf courses was provided in the report.

- *Duration of sampling is sufficient to collect measurable residues but not so excessive so that residue loss occurs.* This criterion was partially met. Measurable chlorothalonil residues, as reported by the investigators, were identified in a majority of the samples collected in the field. However, no field recovery samples were generated in this study. Therefore, it is impossible to quantitatively indicate if chlorothalonil residue losses (i.e., due to degradation/volatilization and various other mechanisms) occurred during the field phase of the study from the dosimeters.

- *Each sampling period should use at least 10 workers.* This criterion was not met. A total of 6 replicates were monitored for each test subject function (i.e., walking players and cart riding players). Therefore, a total of 12 replicates were completed in the entire study for both test subject functions of interest.

- *Dermal exposure reported for each body area monitored for each individual test subject.* This criterion was met. The data were reported in the appropriate format.

- *Total dermal and/or inhalation exposure reported for each individual test subject and for the group as a whole.* This criterion was met. The data were reported in the appropriate format. However, it should be noted that the data were not corrected based on any quality control results and the quality control regimen for the study is inadequate.

Residue Dissipation Data:

- *Duplicate foliar and/or soil samples collected at each collection period.* This

criterion was not met. No foliar dislodgeable residue samples were collected in this study.

- *Sufficient collection times to establish dissipation curve. First sample time taken as soon as sprays dry or dusts settle. Short durations should exist between earlier sample intervals and may lengthen with later samples.* This criterion was not met. No foliar dislodgeable residue samples were collected in this study.

- *Control and baseline foliar or soil samples collected.* This criterion was not met. No foliar dislodgeable residue samples were collected in this study.

- *Foliar residue data expressed as ug or mg/cm^2 leaf surface area.* This criterion was not met. No foliar dislodgeable residue samples were collected in this study.

- *Soil residue data expressed as ug/g of fine soil material.* This criterion is not applicable to this study as no soil samples were collected.

As described above, pertinent data gaps critical to the scientific validity and regulatory acceptability (i.e., Subdivision K compliance) of the study, not addressed above, are presented below. The following issues were identified:

- The study was "conducted and reported in compliance with the Good Laboratory Practice Regulations" identified in 40CFR160. However, no specific explanation was provided regarding which phases of the study were audited/monitored even though a series of audit dates were provided which seemed to span the entire study interval (i.e., 1985 through 1988).

- The description of the study site provided in the report was inadequate. Additional information should be provided regarding the site and the condition/growth stage of the golf course. Plant and site condition parameters can significantly impact potential exposure levels (e.g., heavy foliage may increase exposure levels while less foliage may decrease exposures especially to mowers, various styles of maintenance procedures can also impact personnel contact/exposure levels--irrigation schedules).

- Multiple sequential applications (i.e., 1 week minimum intervals) are allowable by the Daconil 2787 label. However, apparently only a single application was completed prior to each day of golfing (i.e., based on the report apparently the areas which were played were only treated once -- areas treated on each day were played shortly thereafter). Chlorothalonil residues may accumulate over time and present increased risk/hazard levels to golfers and other re-entry personnel as residue levels increase.

- The quality control regimen for the field phase of the study was inadequate even

though a good explanation of some sample collection procedures were provided. No information was provided in the report regarding the calibration of the application equipment. Additionally, the field sample collection regimen/techniques were not described in adequate fashion (e.g., apparati not clearly described, calibration data for the weather equipment were not included, cleaning techniques between replicates, staging area preparation and decontamination).

- No validation procedures were apparently incorporated into the protocol/study to ensure proper GC calibration and operation during the analysis of the field samples. Additionally, the techniques used to determine a standard/calibration curve or single point calibration factor were not described in the report.

- No information was provided regarding the QA/QC procedures used during the characterization of the test material (e.g., facility identification) or when the characterization was completed in relation to the completion of the field phase of the study. Additionally, spray solution samples were not collected in order to verify the concentration of the active ingredient, chlorothalonil, in solution.

- Any procedures used to prepare the dosimeters for the field phase of the study were not described in the report (e.g., pre-extraction of gloves and socks or washing the polyester/cotton coveralls).

- Pre-field phase dosimeter validation data should have been provided for all dosimeter matrices and not just the inhalation monitoring tubes. As a result, an estimation of the reliability of the sample matrices could have been made before going into the field.

- A procedure for calibrating the personal sampling pumps was provided in the study protocol However, there was no indication in the report regarding whether or not the pumps during the field phase of the study were indeed calibrated during activities.

- It appears that the GC retention time varied from @ 1.9 to @ 2.5 minutes during the analysis of the field samples (i.e., variation of @ 25%). No explanation was provided in the report regarding this phenomenom (i.e., matrix effects, column changes, etc.).

- No explanation was provided in the study report regarding the clothing scenario selected for the test subjects (i.e., players). Additionally, the use of a golfing glove is a common practice. However, their use in the study was not adequately justified as, by design, they will mitigate exposure levels by providing an added layer of protection for the player.

- The selection of golf courses in northeastern Ohio was not adequately justified in the report -- management practices may vary significantly due to geographic restrictions. Additionally, the interval the test subjects (i.e., golfers) played behind the Daconil 2787 application was not clearly defined. Cultural/managements practices at some golf courses allow players to almost directly follow spray equipment off of a particular hole thereby increasing the potential for exposure.

To summarize, the post-application (i.e., golfer) exposure study completed in support of the regulatory requirements for chlorothalonil should not be considered acceptable for regulatory purposes by the Agency. This rejection is based on several major criteria including, but not limited to the following: no field recovery data were generated and no laboratory recovery samples were clearly defined in the study report; the dissipation kinetics during the post-application exposure phase of the study were completely ignored; an inadequate number of replicates were completed; the QA/QC regimen during the field phase of the study and during the routine analysis of the field samples was inadequate; the field sites were not described in sufficient detail; no environmental fate data were submitted to support the study protocol; and the selection of northeastern Ohio as the study site was not adequately justified. Additionally, several other inadequacies/inconsistencies were noted in the study results.

Should you have any additional questions please feel free to call at 703-750-3000.

Enclosures:

Correspondence

Study/"A Golfer Exposure Study With CHlorothalonil Used For Golf Course Maintenance - 1985" (MRID 424338-11)

13544

R132840

Chemical: Chlorothalonil

PC Code:
081901

HED File Code: 19050 Versar DER Warning: May not have been QAed by EPA- - CONTRACTOR DRAFT DOCUMENT

Memo Date: 8/1/1993

File ID: 00000000

Accession #: 412-07-0024

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