424338-10

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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 Mixer, Applicator, and Mower Exposure Study With Chlorothalonil For Golf Course Maintenance - 1985" (MRID 424338-10)

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 U (Applicator Exposure Monitoring Requirements) of the Pesticide Assessment Guidelines (U.S. EPA, 1986 & U.S. EPA, 1988).

The following information can be used to identify the study:

Title:	A Mixer, Applicator, and Mower Exposure Study With Chlorothalonil 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: 9/6/88 Field Phase: 8/14/85-9/25/85 Analytical Termination: 1/28/86
Identifying Codes:	EPA MRID 424338-10 SDS Report No.: SDS-2787 SDS Doc. No.: 1148-85-0051-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 workers to chlorothalonil during mixing and applying Daconil 2787 Flowable Fungicide and from mowing turf that had been previously treated. Measurements were made under normal working conditions of (1) airborne concentration of chlorothalonil in the breathing zone and (2) chlorothalonil on gloves, socks, and patches attached to both the inside and outside of clothing worn by each worker."

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 from August 14 through August 28, 1985 while all monitoring was completed at the Quail Hollow course from September 10 through September, 25, 1985. "Each day of mixing and application or mowing was designated as an individual replicate per worker per job function at each golf course. Mixers and applicators were monitored on the day of mixing and application. Monitoring of mowers occured at the first mowing following application (on the day after application) in order to estimate the worst case of potential exposure of mowers to chlorothalonil in the normal operation of the golf courses. Mower exposure on subsequent days was not measured." The monitoring regimen for this study is summarized in the table below:

Study Regimen Summary

Job Function	Number of Replicates Deer Lake	Quail Hollow	Total
Fairway Applicator	3	3	6
Greens Applicator	3	3	6
Mixer	3	3	6
Fairway Mower	3	6	9
Greens Mower	7	9	16

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.

After the applications were complete the fairways and the greens were both mowed as described above. The equipment used to mow and the area which was mowed for each replicate differed at each site. The equipment which was used is described below:

- *Deer Lake (Greens):* Toro, Greenmaster - 21" unit model #04116-9001 walking system.

- *Deer Lake (Fairways):* Worthington Gang Mower, 7x30" units for a total cut width of 17', tractor pull system.

- *Quail Hollow (Greens):* Jacobsen - Greensmower 22" unit walking, Model #62230.

- *Quail Hollow (Greens Collar Mower):* Toro Triplex Greensmaster-GM3, total cut width 69 3/4".

- *Quail Hollow (Fairways):* Toro Park Master, self-propelled, 18'6" width cut, 9 gang unit.

Climatological data including "weather condition, temperature, relative humidity, barometric pressure, wind speed, and wind direction were taken several times during each day that a study activity was performed." 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 65°F to 79°F with concurrent humidity levels ranging from 61% to 94%. At Quail Hollow during all operations, temperatures ranged from 45°F to 75°F with concurrent humidity levels ranging from 40% to 93%.

According to the study report, "each worker wore a jumpsuit with long sleeves and ankle length trousers, made of a poplar weave of 65% Kodel polyester/35% combed cotton permanent press as a 7.5 oz. white twill material. They were obtained from Elin Uniform Manufacturing Company, Rochester, Indianna 46975 as Men's Long Sleeve Jumpsuit - order number 9807.

The following body areas were sampled for all workers:

- Head -- patch outside cap front

- Chest -- patches inside and outside jumpsuit

- Back -- patches inside and outside jumpsuit

- Shoulder -- patches outside jumpsuit (right and left)

- Upper Arm -- patches outside jumpsuit (right and left)

- Forearm -- patches outside jumpsuit (right and left)
  patches inside on sweatbands (right and left)

- Hand -- cotton gloves (right and left)

- Work gloves -- (right and left) for mixers and applicators
- Thigh -- patches outside jumpsuit (right and left)
- Ankle -- patches inside and outside jumpsuit (right and left)
- Foot -- inside sock (right and left)
- Foot -- outside sock (right and left) for greens applicators and all mowers
- Leg -- patches inside on sweatbands (right and left)

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. The foil and gauze were taped to the denim with fiber tape. The completed patch was then attached to the junpsuit with safety pins. Inside patches were attached with the uncovered gauze facing to the cloth of the jumpsuit. "

Additionally, "potential hand exposure was evaluated by the wearing of light cotton gloves, 100% cotton rib knit, cut to a standard length of 12 inches, obtainied from John Plant Company, Ramseur, North Carolina 27316 as Men's Light Weight Gloves - order number 216X. Work gloves were worn over the light cotton gloves by mixers and applicators only, as specified on the Daconil 2787 label. Work gloves, also assayed, were of heavy cotton, obtained from Standard Glove and Safety Equipment Company as 802-208-BT cotton work gloves, stock number 19-36820-9200."

Foot exposure was also "evaluated by analysis of light cotton socks worn under the sock normally worn by the worker. Inner socks, 68% cotton/32% nylon, style-FMCS (ultra-thin), were obtained from Koenig Sports, Great Lakes Mall, Mentor, Ohio 44060. The outer sock was collected from some workers and divided into an upper and lower portion using the upper limit of the shoe as the dividing line. Outer socks, 100% nylon-knee length, were obtained from Sears, Great Lakes Mall, Mentor, Ohio 44060."

Little description was provided in the study report regarding the inhalation monitoring regimen. However, the following was excerpted from the study 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 worker sampled. Air will be drawn through the collection system by a portable sampling pump attached to the worker. In practice, the portable sampling pump will be placed in a rear pocket of the jumpsuit with the connection tube coming up over the worker's shoulder. The open end of the collection system will be fastened to the collar or front of the jumpsuit 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 to 2.5 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 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 worker will be placed in the same sample bag." Additionally, the protocol indicated "the actual obtaining and bagging of the respiratory sample [Filter cassettes and Chromsorb resin filled tubes] have been previously detailed under "Field Sample Collection And Identification-Respiratory". However, no explanation of this procedure was included in the referenced section of the protocol.

According to the protocol, "the analytical portion of this study will [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 dermal gauze patches, gloves (work and inner), socks (upper, lower, and inner), air filters and adsorbent tubes by placing them into extracting jars and shaking with pesticide grade toluene for a minimum 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 or 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 equipped with NPD (^{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 180 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 for 8 hours with the personal sampling pumps to simulate field sampling, and (2) collection efficiency -- a series of 2 experiments 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, 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). Additionally, "previous stability studies (not reported here) submitted to and reviewed by the U.S. Environmental Protection Agency have demonstrated the chlorothalonil residues on agronomic crops are stable in frozen storage for up to at least 14 months." 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. [Note: The storage stability results are presented and reviewed in a separate memo as these results are applicable to several of the studies submitted in support of chlorothalonil currently being reviewed by the Agency.]

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 - 0.18	12	86.3	7.56
Gauze Patches[6]	3.40 - 5000.0	96	98.1	8.55
Work Gloves	20.0 - 400000	12	94.8	8.36
Inner Cotton Gloves	20.0 - 5000.0	13	95.0	10.17
Outer Upper Socks	20.0 - 1000.0	13	95.1	9.47
Outer Lower Socks	16.0 - 200.0	12	100.7	7.48
Inner Socks	16.0 - 5000.0	13	99.3	7.05
Cellulose Filters	0.018 - 10.0	4	87.0	10.52

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 0.051 - 5.865 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
All Socks	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 Subdivisions K and U of the Pesticide Assessment Guidelines (U.S. EPA, 1984/U.S. EPA, 1986/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 Subdivisions K and U. The lists are based on the "Checklist for Applicator Monitoring Data", 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/OREB. 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).

- *Quantity of active ingredient handled and duration of monitoring period reported for each replication.* This criterion was met as the required data were reported in the proper format.

- *Clothing worn by each study participant and location of dosimeters reported.* This criterion was partially met. All dermal/inhalation monitoring devices were adequately described as were the jumpsuits worn as a shell by the test subjects to which the dosimeters were affixed. However, any additional personal clothing worn by each test subject was not described including their shoes (i.e., foot exposure levels were determined in this study and various types of shoes could affect the corresponding exposure levels).

- *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.

- *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.

- *Quantitative level of detection is at least 1ug/cm^2.* This criterion was partially met. The LOD for all matrices appeared to be adequately sensitive as did the quantitation limit, as defined by Versar as the lowest fortification level for each sample matrix (i.e., quantifiable chlorothalonil residues were reported in a majority of the field samples). However, the techniques used by the investigators to define the LOD were not reported. Additionally, the investigators should have defined a quantitation limit based on the available QA/QC data.

- *Storage of samples consistent with storage stability data.* 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 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.

- *Efficiency of extraction in laboratory provided as a mean plus or minus one standard deviation. Lower 95% confidence limit is not less than 70% based on a minimum of seven replications per fortification level or prior Agency approval of extraction methodology provided.* This criterion was partially met. The required number of recovery samples was not generated for any sample matrix except for most fortification levels for the gauze patch samples and the highest fortification level in the collection efficiency test for the sorbent tubes (i.e., inhalation monitors). Based on the available data the lower limit of the 95% confidence interval appears to be greater than the 70% minimum. Additionally, mean and standard deviation values were presented for each sample matrix.

- *At least one field fortification sample per worker per monitoring period per*

fortification level for each matrix must be generated. Additionally, at least one field blank per worker per monitoring period per matrix must be collected. This criterion was not met. 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.

- *When collecting urine for biological monitoring, collection should involve 24 hour samples. A minimum of one baseline, pre-exposure 24 hour sample must be collected. 24 hour samples must be collected for the day of application and for sufficient days postapplication as determined by the excretion profile of the pesticide.* This criterion is not applicable to this study as there was no biological component to 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). Biological monitoring is consistent with and supported by pharmacokinetic data accepted by the Agency.* 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). 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.

- *For outdoor exposure monitoring of mixer/loaders or applicators, at least 5 replicates at each of at least three sites for each job function with the exception of pilots should be completed.* Pilots should have at least 3 replications at each of at least 3 sites. This criterion was not met. Only 2 study sites were utilized in the study. Additionally, an insufficient number of replicates were completed for each job function. Only 6 mixer/loader and 12 applicator replicates were completed (i.e., 6 fairway and 6 greens applications, however, the equipment used was similar).

- *For indoor exposure monitoring of mixer/loaders or applicators at least 5 replicates at each of at least 3 sites for each job function should be completed.* This criterion was not applicable to the study as no indoor monitoring replicates were completed in this study.

- *For post-application monitoring, each sampling period should use at least 10 workers.* This criterion was partially met. A total of 16 replicates were monitored during the mowing of the greens (i.e., using commercial type pushing mowers). However, only 9 replicates were completed during fairway mowing using standard commercial type riding equipment.

- *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 and U 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 mowing (i.e., based on the report apparently the areas which were mowed were only treated once -- areas treated on each day were mowed the following day). Chlorothalonil residues may accumulate over time and present increased risk/hazard levels to mowers 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).

- The report indicated that "with the exception of the Quail Hollow fairway applicator, who utilized a Myers air assisted broadcast sprayer, mixers had the highest estimated actual exposure to chlorothalonil." The differences between this sprayer and the the other spray equipment used in the study were not clearly defined based on the descriptions provided in the report. In fact, this piece of equipment was described as a typical sprayer outfitted with a "high pressure piston pump." "Air assisted" is a term which connotates some sort of airblast equipment.

- 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 @ 1.8 to @ 2.4 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.).

To summarize, the combined mixer/loader, applicator and post-application (i.e., mower) 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 during the mixer/loader, applicator

phase of the study coupled with the number of study sites was unacceptable; the QA/QC regimen during the field phase of the study and during the routine analysis of the field samples was inadequate; the field site was 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 Mixer, Applicator and Mower Exposure Study with Chlorothalonil For Golf COurse Maintenance - 1985" (MRID 424338-01)

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R132835

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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