US EPA ARCHIVE DOCUMENT

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

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 25, 2002

Memorandum

SUBJECT: **Tetrachlorvinphos: Re-evaluation of** *Determination of the Dislodgeability of Tetrachlorvinphos (TCVP) from the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol*; MRID 454855-01. PC Code 083701; DP Barcode D277543, Submission S597121

FROM: Susan Hanley, Chemist
Reregistration Branch 1
Health Effects Division (7509C)

THRU: Whang Phang, Branch Senior Scientist
Reregistration Branch1
Health Effects Division (7509C)

TO: Demson Fuller, Chemical Review Manager
Special Review and Reregistration Division (7508C)

Attached is a review of the dislodgeable fur (dog) residue(DfR) studies submitted by Hartz Mountain Corporation (Hartz), MRID 454855-01. The primary review was completed by Versar Inc. on November 19, 2001 under supervision of HED. Since completion of the secondary review, December 10, 2001, corrected calculations and explanation of data has been added.

Executive Summary

This study was conducted to determine the dislodgeability of tetrachlorvinphos (TCVP) residue from a pet's fur. The study data were generated by Hartz to refine the Agency's postapplication exposure assessment for toddlers. Powder, pump-spray and aerosol-spray market-ready pet insecticide products were used on dogs to determine the amount of TCVP residue available on the fur, and the amount of residue removed from the fur during petting. Since HED calculates postapplication exposures to treated pets assuming a 30 lb dog, the submitted data were used to determine the application rate per pound animal; the initial percent of TCVP applied subsequently removed by petting was used to calculate postapplication exposure. Table 1 contains the mg TCVP/ lb dog calculation and statistical distributions, and Table 2 contains the regression analysis results for the dissipation of TCVP removal from fur. Table 3 has the calculations of predicted percent of applied TCVP available and removed from petting dog.

Some deficiencies were recognized in this study. The study only sampled 5 dogs per product, and only one application was applied when multiple applications are allowed by label. Multiple applications would reveal if a build up of TCVP residues occurs. In addition, because the powder product was pre-measured, the data do not reflect natural variation in application rate expected to occur when label directions are followed.

Summary

Three market-ready products were used to demonstrate the dislodgeable residue of TCVP from dog fur. A pump spray, an aerosol or a powder TCVP product were each applied to five dogs. Four (4) hours after treatment each dog had spots of fur clipped from one side of the body for fur residues sampling while, on the other side, the full length of the body was stroked by hand 5 times to determine the amount of TCVP dislodgeable by petting. Fur and handwipe samples were collected and sent to the laboratory for extraction. The fur clippings and petting-handwipe samples were taken at each collection time, at 1, 2, 4, 8, 16 and 32 days after treatment (DAT).

Samples were not dislodged or frozen at the site or for shipment. The samples were to be analyzed within 5 days of collection; however; collection, shipment and analysis dates were not provided in the study report. The attached Versar review (Attachment A) contains the information on the analytical methods and recovery values. The "field" fortification samples were sent from the Hartz laboratory to the field site and back to the laboratory. These samples support the stability of TCVP on fur and gauze pads used for handwipes. The recoveries for fur averaged 98.9 ± 5.2 percent and each level tested was above 90 percent recovery. Handwipe media recovery averaged 96.9 ± 12.1 percent. The medium TCVP concentration level on handwipe media had a recovery of 88.6 percent and samples in this range were corrected.

Non-detect samples were assigned a value of ½ limit of detection (LOD) which was supplied in the method validation section. The LOD for the fur samples was 0.5 ug; for the

handwipe samples LOD was 0.62 µg. Typical units for HED postapplication assessments are µg/cm^2, therefore the µg TCVP measured was divided by the surface area of the sample, for each sample taken. This resulted in individual LODs for each of the samples. One fur sample was non-detect (DAT 32, pump spray) and was assigned a value of 0.0039 µg/cm^2. Three of the 5 handwipe samples on DAT 32 were non-detect and were assigned ½ LOD values, ranging between 0.0030 and 0.0039 µg/cm^2.

These residential pet treatment products do not have precise application rates (e.g., number of pump strokes for medium size dogs, number of seconds to apply an aerosol, etc.), and the application rates tend to vary. The powder product was supplied in 1 ounce samples for the study, market ready products are supplied in 4 ounce packages. The subjectivity of the applicator for the powder product application was compromised because of the limited amount of product available. To determine the amount of TCVP applied, each product was weighed before and after treatment.

Table 1: Amount of Product Used and TCVP Applied per Pound Dog.

	Powder			Aerosol Used			Pump Spray Used		
Dog	*Weight (lb)	TCVP Applied (mg)	mg/lb Dog[a]	Weight (lb)	TCVP Applied (mg)	mg/lb Dog	Weight (lb)	TCVP Applied (mg)	mg/lb Dog
1	37	848	23	35	375	11	35	345	10
2	37	838	23	39	419	11	39	382	10
3	38	826	22	35	525	15	36	347	10
4	33	819	25	36	515	14	35	348	10
5	41	856	21	36	444	12	36	331	9
Average	37	837	23	36	456	13	36	350	10
Geometric Mean	37	837	23	36	452	12	36	350	10
95%ile	40	854	24	39	523	15	38	375	10
50%ile	37	838	23	36	444	12	36	347	10

* From study data, not in Versar review.

a mg/lb dog = TCVP applied (mg) / Weight of Dog (lb)

HED used the data from the study to calculate the regression curve for TCVP dissipation on the fur and removal by hand. Table 2 contains the DAT 0 results and regression statistics that resulted from analyzing the data.

Table 2: TCVP Predicted Residues on Fur and Hand (per Regression Analysis).

DAT	Powder (µg/cm²)		Aerosol (µg/cm²)		Pump Spray (µg/cm²)	
	Hand	Fur	Hand	Fur	Hand	Fur
	R^2 =0.985 Slope = -0.267	R^2=0.98 Slope = -0.197	R^2=0.94 Slope= -0.382	R^2=0.939 Slope = -0.169	R^2= 0.947 Slope=-0.405	R^2 =0.838 Slope -0.149
0	0.33	53	1.40	43	1.0	20
Study Results (average residue)	0.31	73	1.60	73	2.01	49

For toddler postapplication exposure, HED is concerned with levels of residue immediately after treatment. Using the predicted hand residues, the percent of applied TCVP removed by petting was calculated for each product, as shown in Table 3. First, from Table 1 the average dog weight was used to calculate the average dog surface area. Using the calculated surface area, the average application amount/lb dog is applied to the average size dog and spread evenly over the surface area of the average dog. Finally, the predicted petting hand residue (µg/cm²) was compared to the applied amount (µg/cm²) to calculate the percent of applied removed by petting. The percent of applied removed by petting can be used to calculate postapplication exposure from a treated pet resulting from petting, hugging and hand-to-mouth behaviors.

Table 3: Predicted Percentages of TCVP available

Time (Days)	Animal Avg Surface Area (cm²)	Avg TCVP applied (mg)	µg/cm² Applied	Fur Residue (µg/cm²)	% of Applied Available on Fur	Hand Residue (µg/cm²)	**% of Applied Transferred to Hand**	% Available on Fur Transferred to Hand
				Pump Spray				
0	6800	350	51	20	39	1.0	**1.94**	5.0
				Aerosol				
0	6800	456	67	43	64	1.4	**2.09**	3.3
				Powder				
0	6900	837	121	53	44	0.33	**0.27**	0.62

a Average Surface Area (cm²) = 12.3 [Average Weight (g)]$^{0.667}$. Exposure Factors Handbook, Mammalian Surface Area

b Applied Concentration (µg/cm²)= [Avg TCVP Applied (mg) ÷ Average Surface Area (cm²)] * 1000 µg/mg.

c Hand Residue and Fur Residue (µg/cm²) predicted by study data regression analysis as presented by Versar

d % of Applied Available (on fur) = [Fur Residue (µg/cm²) ÷ Applied Concentration (µg/cm²)] * 100%.

e % of Applied Transferred to Hand =[Hand Residue (µg/cm²) ÷ Applied Concentration (µg/cm²)] * 100%

f % Available Transferred to Hand = [Hand Residue (µg/cm²) ÷ Fur Residue (µg/cm²)] *100%

Conclusion

No direct regulations or study standards apply to postapplication treated pet exposure. This study followed Subdivision K (currently referred to as Series 875 Group B)guidelines for dislodgeable foliar residue studies to quantify fur residues and transferability. The data are of sufficient scientific quality to be used to determine TCVP postapplication exposure, with some caveats on study acceptability listed below:

* Few replicates (both application and dislodgeability) were completed for each;

* Only one application was done at testing time, but multiple applications are allowed on labels;

* The study powder application container had 1 ounce of product and the applicator was directed to use all of the product in the container. The market ready container contains 4 ounces of product, and the amount applied to pets in the home would likely be more variable than the study allowed;

* Only one applicator was used in the study. Since the application rate is largely subjective, one applicator does not reveal the range of application rates possible;

* The pump spray and aerosol spray have the same formula, however, the pump spray is removed from the fur more readily than the aerosol. No explanation of this difference was mentioned, but issues such as initial droplet size and application method may be factors;

* The laboratory recovery testing was performed, but results were not reported;

* Information on animal housing does not include whether outdoor access was available, which could influence the rate of dissipation.

Recommendations

The study results should be used in postapplication exposure assessment. Hartz Mountain Corporation waived confidentiality on the data in this study, so information from this study may be used for other active ingredient pet products. Attached is the Verar primary review of the study for further data references.

Reviewer: Teri Schaeffer/Marit Espevik **Date November 19, 2001**

STUDY TYPE: Determination of Dislodgeable Residue on Dog Fur Treated with Hartz® 2 in 1® Flea and Tick Powder for Dogs, Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs, and Control Pet Care System® Flea and Tick Repellent Spray for Dogs.

TEST MATERIAL: *Hartz® 2 in 1® Flea and Tick Powder for Dogs* is formulated as a powder containing 3.0% of the active ingredient (Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate.

Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs is formulated as a liquid aerosol spray containing 1.08% of the active ingredient (Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate.

Control Pet Care System® Flea and Tick Repellent Spray for Dogs is formulated as a liquid pump spray containing 1.08% of the active ingredient (Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate.

SYNONYMS: Rabon, tetrachlorvinphos, TCVP, CAS No. 22248-79-9.

CITATION:

Study Director/Author:	Kathleen McKeown Senior Manager, Analytical R&D and Quality Control Hartz Mountain Corporation
Title:	*Determination of the Dislodgeability of Tetrachlorvinphos (TCVP) From the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol*
Report Date:	June 13, 2001
Analytical Laboratory:	The Hartz Mountain Corporation 192 Bloomfield Avenue Bloomfield, NJ 07003
Identifying Codes:	MRID 45485501; Hartz Test #1555; Unpublished

SPONSOR: Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07003

EXECUTIVE SUMMARY:

This study was designed to characterize the rate of transfer of tetrachlorvinphos (TCVP) from pet fur to the human hand following the application of an aerosol, spray, or powder insecticide product. The total amount of TCVP found on the fur of the dogs was determined by a "split-back" methodology after a single treatment of one of the three types of product. The study concurrently determined the amount of TCVP dislodged onto the hand during stroking of the animals. Both of these parameters were measured at 8 sampling intervals which were performed at pretreatment and at 4 hours, 1 day, 2 days, 4 days, 8 days, 16 days and 32 days after treatment (DAT). Five volunteer applicators and fifteen dogs were used in the study. The application method used was relevant to the use pattern proposed for these three products.

The Registrant did not correct the residue data for field fortification recoveries because the overall recoveries were above 90 percent. Versar corrected the handwipe residue data for the mid-level recovery of 88.6%. EPA requested that the residue data be converted from µg (handwipe residue data units) and µg/g (fur residue data units) to µg/cm^2 and that Versar conduct linear regressions. The half-lives for the TCVP residues found on fur for all three products ranged from 3.42 days (pump product) to 3.98 days (aerosol product). The half-lives for the dislodgeable TCVP residues found on the hand after treatment ranged from 2.81 days (aerosol product) to 3.52 days (powder product).

Hartz® 2 in 1® Flea and Tick Powder for Dogs - The average mean residual TCVP found on the dog fur peaked at 72.79 µg/cm^2 four hours after the treatment. The average mean dropped to 0.12 µg/cm^2 by DAT 32. The average mean dislodgeable TCVP residue from the handwipe samples peaked at 0.312 µg/cm^2 four hours after treatment and dropped to 0.001 µg/cm^2 by DAT 32. The percent TCVP dislodged by the hand after treatment was highest at 1.49% at the 4 hour sampling interval (Applicator A). All of the dislodgeable TCVP percentages dropped to 0.01 by DAT 16.

Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs - The average mean residual TCVP found on the dog fur peaked at 73.17 µg/cm^2 four hours after the treatment. The average mean dropped to 0.28 µg/cm^2 by DAT 32. The average mean dislodgeable TCVP residue from the handwipe samples peaked at 1.58 µg/cm^2 four hours after treatment and dropped to 0.001 µg/cm^2 by DAT 32. The percent TCVP dislodged by the hand after treatment was highest at 4.35% at the 4 hour sampling interval (Applicator B). All of the dislodgeable TCVP percentages dropped to zero by DAT 32. One of the dogs expired between the day 16 and day 32 sampling interval. The cause of death was long-term advanced cancer according to the necropsy report.

Control Pet Care System® Flea and Tick Repellent Spray for Dogs - The average mean residual TCVP found on the dog fur peaked at 49.30 µg/cm^2 four hours after the treatment. The average mean dropped to 0.27 µg/cm^2 by DAT 32. The average mean dislodgeable TCVP residue from the handwipe samples peaked at 2.01 µg/cm^2 four hours after treatment and dropped to 0.001 µg/cm^2 by DAT 32. The percent TCVP dislodged by the hand after treatment was highest at

11.11% at the 4 hour sampling interval (Applicator A). All of the dislodgeable TCVP percentages dropped to 0.01 by DAT 16.

The Series 875 Guidelines do not apply directly to this type of study. However, Versar reviewed the study for compliance with Series 875 Group B (i.e., guidelines for dislodgeable residues from agricultural foliage and quality assurance were used) and found that the study met most of the guidelines. The following issues of potential concern were identified: (1) Fortification samples were spiked in the Hartz laboratory and then shipped to the testing facility. They were not fortified in the field. However, these samples served to support the stability TCVP in the matrix (handwipe or dog fur); (2) Sample collection dates and sample analysis dates were not provided in the study report to verify storage stability claims; (3) There was no information on the test sites in the study report; (4) Weather data were not provided in the study report; (5) The product labels allow for multiple applications of the test product a few days apart. In this study, only one application was made per dog; and (6) The Registrant reported that laboratory fortified samples were used concurrently with sample analyses. However, the recovery results for these laboratory fortified samples were not provided in the study report.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided and there were no deviations to GLP compliancy noted.

CONCURRENT EXPOSURE STUDY?: Yes.

WAS AIR SAMPLING CONDUCTED IN CONJUNCTION WITH SURFACE SAMPLING?: No

GUIDELINE OR PROTOCOL FOLLOWED:

This study was conducted according to Hartz Protocol 2001-3 (Determination of the Dislodgeability of Tetrachlorvinphos (TCVP) from the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol). According to the Registrant this protocol is consistent with EPA guidelines in Series 875 Group B.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

The test materials were supplied to the field site by the Registrant. According to the protocol, materials were to be stored under ambient temperature and humidity. Specific site storage conditions were not mentioned in the Study Report.

Hartz® 2 in 1® Flea and Tick Powder for Dogs

Formulation:	Formulated as a powder
Lot/Batch # formulation:	Lot # MR04011
Formulation guarantee:	Actual TCVP content was 3.11%
CAS #(s):	22248-79-9
Other Relevant Information:	EPA Reg. #2596-79; Test Sample TS# 12002; intended for residential use.

Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs

Formulation:	Formulated as a liquid aerosol spray
Lot/Batch # formulation:	Lot # MR04611
Formulation guarantee:	Actual TCVP content was 1.04%
CAS #(s):	22248-79-9
Other Relevant Information:	EPA Reg. #2596-122; TS# 12006; intended for residential use.

Control Pet Care System® Flea and Tick Repellent Spray for Dogs

Formulation:	Formulated as a liquid pump spray
Lot/Batch # formulation:	Lot # 605911
Formulation guarantee:	Actual TCVP content was 1.09%
CAS #(s):	22248-79-9
Other Relevant Information:	EPA Reg. #2596-125; TS# 12007; intended for residential use.

2. Relevance of Test Material to Proposed Formulation(s):

The test products used for this study are the same product names and formulations that appear on the test product labels which are registered for residential consumer use.

B. STUDY DESIGN

There were two deviations to the study protocol. The first deviation involved the death of one of the dogs (death unrelated to study), thus preventing the final (Day 32) collection of wipe and hair samples after treatment with Flea and Tick Aerosol TS# 12006. The second deviation involved the loss of one handwipe blank sample and one mid-level QA/QC sample due to breakage of sampling containers in transit. The remaining samples were found to be acceptable. None of the deviations had any adverse affects on the study integrity.

1. Number and type of individuals and test animals monitored:

Five adult individuals participated in this study. Consent of all participants was obtained in writing prior to participating in the study.

Fifteen dogs were used as test animals (9 males and 6 females). The dogs were all mixed breeds. Each dog was medium sized and weighed approximately 30 pounds. The dogs had been acclimated to the testing facility for a minimum of 21 days prior to the study. The dogs were housed in runs (3' x 10'), which had concrete floors and cyclone fencing sides. Food and water were made available to the dogs ad libitum and the dogs were observed daily. According to the Registrant, this study was in compliance with all applicable sections of the Animal Welfare Act.

2. Application Rates and Regimes

Residential or Commercial Applicator?: Residential

Application rate(s): A single treatment of one of the three products was made to each test animal. These products were all applied according to label directions. The actual amount of product used in each treatment was determined by weighing the container before and after use (weighed out to the nearest 0.01 gram).

Hartz® 2 in 1® Flea and Tick Powder for Dogs -

The target application rate was one ounce of powder per dog The measured amount of product used per dog ranged from 26.34 grams to 27.54 grams.

Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs -

The target application rate was approximately a 45 second spray per dog. The measured amount of product used per dog ranged from 36.39 grams to 50.48 grams.

Control Pet Care System® Flea and Tick Repellent Spray for Dogs -

The target application rate was approximately 40 pump strokes per dog. The measured amount of product used per dog ranged from 30.39 grams to 35.03 grams.

Application Regime:

Hartz® 2 in 1® Flea and Tick Powder for Dogs -

The entire dog was dusted beginning at the head and working back towards the tail. The fur was ruffled on dogs with long hair so that the powder would reach the skin. The feet and legs were treated as well

Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs -

The aerosol can was held approximately 6 to 10 inches from the dog and was sprayed lightly over the entire body. The spray was directed against the natural lay of the hair to cause fluffing of the coat which enabled the product to penetrate to the skin.

Control Pet Care System® Flea and Tick Repellent Spray for Dogs -

The pump spray bottle was held approximately 6 inches from the dog. The entire coat of the dog was sprayed while pressing the dispenser with quick short strokes. The bottle was moved while spraying to allow for an even coverage. The spray was applied lightly and rubbed into the dog's coat to enable penetration of the product to the dog's skin.

Application Equipment:

Hartz® 2 in 1® Flea and Tick Powder for Dogs -

Applied using the commercial container, a cardboard canister with a plastic shaker top.

Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs -

Applied using the commercial container, an aerosol spray can.

Control Pet Care System® Flea and Tick Repellent Spray for Dogs -

Applied using the commercial container, a plastic pump spray bottle.

Equipment Calibration Procedures: Not applicable.

3. Dislodgeable Residue Sampling Procedures

Sampling Surfaces: Sampling was done by wiping the stroking hand of each of the study participants with handwipes and by collecting fur from each of the dogs at different sampling intervals after the treatment.

- Replicates per sampling interval: There were 5 replicates per product tested per sampling interval.

- Number of sampling intervals: There was 1 sampling done prior to the application of the test product and 7 sampling intervals after the application of the test product.

Sampling Intervals: Blank or baseline samples were collected just prior to the treatment. Sampling continued at 4 hours after treatment, and on Days 1, 2, 4, 8, 16, and 32 after the treatment.

Area Sampled: Table 1 provides a summary of the calculated stroking areas of each dog used in the study. This stroking area (inch^2) was calculated by multiplying the length of the study participant's hand in inches by the length of the dog in inches.

Four subsections were shaved on each dog at each fur sampling interval. According to the study protocol, the subsections shaved were to be similar in size and the total composite sample from all four subsections was to contain at a minimum of 1 gram of fur. Table 2 provides a summary of the surface areas from which the fur was sampled on each dog.

Table 1. Stroking Area for Each Test Dog

Study Participant ID	Length of Hand (inches)	Dog ID	Length of Dog (inches)	Stroking Area (inches^2)
A	6.5	317p	18.5	120.25
		315a	19	123.5
		313s	19.5	126.75
B	7	271p	19.5	136.5
		304a	18.25	127.75
		258s	23	161
C	7	267p	18.75	131.25
		279a	18.75	131.25
		306s	18	126
D	6.5	285p	19.25	125.13
		262a	19.5	126.75
		223s	19.5	126.75
E	6.75	260p	19.25	129.94
		283a	21.25	143.44
		257s	19.25	129.94

p - dogs treated with powdered test product.
a - dogs treated with aerosol test product.
s - dogs treated with pump spray test product.

Table 2. Average Total Surface Area of Dogs Shaved for Fur Samples.

Dog ID	Range of Total Areas per Sampling Interval (Inches^2)	Average Total Surface Area Across all Sampling Intervals (Inches^2)
317p	4.01 - 6.98	5.4
271p	3.22 - 4.74	4.13
267p	3.91 - 6.68	4.15
285p	4.38 - 5.72	4.8
260p	3.00 - 5.32	4.02
315a	3.43 - 5.09	4.49
304a	4.40 - 7.74	5.97
279a	3.56 - 5.39	4.37
262a	4.70 - 7.00	5.78
283a	3.67 - 6.07	4.66
313s	3.83 - 9.97	6.33
258s	2.66 - 7.07	4.09
306s	5.66 - 8.25	6.81
223s	4.15 - 5.98	5.01
257s	4.35 - 6.94	6.04

p - dogs treated with powdered test product.
a - dogs treated with aerosol test product.
s - dogs treated with pump spray test product.

Method and Equipment: The sampling method used to determine the amount of TCVP dislodged onto the study participant's hands was based on the Geno et al., 1996 protocol. Hand wipes were used to collect the TCVP residues on the hands. Fur was collected to measure the amount of TCVP residues found on each dog.

Sampling Procedure(s) :

Hand - At various times following application, each of the five study participants stroked a treated dog 5 times from head to rump using one hand, and wiped the hand by using a gauze pad moistened with methanol. The study participant placed the gauze pad into a 60 ml bottle. The study participant took a second gauze pad and wiped each digit, the palm, and the back of the hand and placed it into the same bottle with the first gauze pad. These steps were repeated on each day of sampling.

Fur - Once the study participant was done stroking the dog, the fur on the other side of the dog's back was sampled. Fur samples were taken from each of four subsections of the unstroked side of the dog's back using an Oster Clipper. The fur was clipped to skin level. Four subsections were shaved on each dog at each fur sampling interval. The subsections shaved were similar in size and the total composite sample from all four subsections was to contain 1 gram of fur. The total hair sample was placed into a 60 ml bottle. The weight of the hair sample was measured to the nearest 0.01 gram and the length and width of the total area shaven were measured to the nearest 0.1 inch. This procedure was repeated on each sampling day.

Other Relevant Information: According to the Registrant, a previous study found that the length of the dog's hair was not a factor in the dislodgeability of TCVP.

4. Sample Handling

The handwipe samples were collected into 60 ml bottles. The bottles were labelled with the test number, product, test animal number, applicator ID number, stroking hand (left or right), and collection time. These samples were shipped to Hartz Mountain Corporation by next-day service for analysis.

Bottles of fur were labelled with test number, product, test animal number, applicator ID number, collection time and weight of the hair sample. These samples were shipped to Hartz Mountain Corporation by next-day service for analysis.

According to the protocol, all of the samples received at the Hartz lab were to be analyzed within 5 days. All of the samples were stored at room temperature. Sample collection dates, shipment dates, and analysis dates were not provided in the study report.

5. Analytical Methodology

Extraction method(s): A 25% ethyl acetate in hexane extraction solution was prepared and 25 ml was added to each of the 60 ml sample jars. The sample jars were shaken for at least an hour. The animal fur samples were either centrifuged or filtered prior to analysis. For the gauze pads (handwipes), a 1.0 ml aliquot was transferred into a 5 ml screw cap test tub and placed in a water bath. These 1.0 ml aliquots were evaporated to dryness with a stream of dry air and 1.0 ml of the 25% ethyl acetate in hexane solution was added and mixed until the residue was fully dissolved.

Detection method(s): See Table 3.

Table 3. Summary of HPLC Chromatographic Conditions

HPLC Column	Silica (4.6 mm x 12.5 cm), 5 µ, Partisphere from Watman
Detector	UV at 254 nm
Injection Volume	75 µL
Retention Time	TCVP = 2.08 minutes
Flow Rate	2 ml/min
Run Time	Approximately 3 minutes
Linear Range	0.04 to 0.8 µg/ml

Method validation:

The analytical method used was Test Method TM # 413-2. The method was validated for the determination of TCVP residues on filters, PUF plugs, gauze pads and animal fur prior to the collection of the samples for this study. This study review is only concerned with results for the gauze pads and animal fur. The validated Limit of Detection (LOD) was 0.02 µg/ml. The validated Limit of Quantification (LOQ) was 0.04 µg/ml.

The working concentration range for the gauze pad (handwipe) samples was 1.0 µg TCVP to 5000 µg TCVP (maximum anticipated level). The accuracy was demonstrated by the average TCVP percent recoveries for each of the three (LOQ, 10 x LOQ, 5000 x LOQ) fortification levels which were 98.5, 109.4, and 106.3%, respectively. The precision was demonstrated by the overall Standard Deviation of the TCVP percent recoveries for the three fortification levels, which was 7.1.

The working concentration range for the animal fur samples was 1.0 µg TCVP to 8000 µg TCVP (maximum anticipated level). The accuracy was demonstrated by the average TCVP percent recoveries for each of the three (LOQ, 10 x LOQ, 8000 x LOQ) fortification levels which were 108, 109.7, and 100.3%, respectively. The precision was demonstrated by the overall Standard Deviation of the TCVP percent recoveries for the three fortification levels, which was 4.8.

The stability of TCVP in the mobile phase (25% Ethyl Acetate in Hexane) was also exhibited by fortifying three replicates at two fortification levels and storing them up to 28 days (samples were analyzed 1, 5, 7, and 28 days after fortification). TCVP recoveries across all fortification levels and all days stored ranged from 98.2 to 112.3 percent.

Instrument performance and calibration:

A set of calibration standards was run with each set of samples. The calibration curve consisted of 5 standards with approximate concentrations of 0.8, 0.4, 0.16, 0.08, and 0.04 µg/ml. According to the protocol, the correlation coefficient for the calibration standards were found to be 0.99 or higher.

6. <u>Quality Control:</u>

Lab Recovery: Two fortified samples were prepared for each matrix (at the LOQ (1 µg) and 20 times the LOQ (20 µg)). One fortified sample at each fortification level was analyzed concurrently with every sample set. However, the percent recoveries for these laboratory samples were not reported in the study report.

Field blanks: Three field blanks were prepared for each matrix (handwipe and fur) whenever field fortification samples were prepared. TCVP residues were not detected above the LOD in any of the blanks.

Field recovery:

The "field" fortified samples were prepared at the Hartz laboratory and shipped to the testing facility. Triplicate handwipe and fur samples were fortified at three fortification levels. The handwipes were fortified at 10 µg (low), 500 µg (medium), and 2000 µg (high). The fortified fur samples were spiked at 10 µg (low), 500 µg (medium), and 8000 µg (high). The "field" fortification samples were prepared according to protocol # 01-2 and Validation Test Method 413-2. Once received by the testing facility, the fortified samples were stored at room temperature for 5 days (the maximum number of days the field samples were to be held at the facility). After storage, the fortified samples were shipped along with the field samples back to the Hertz laboratory. The fortified samples were stored at the Hertz laboratory for an additional 5 days under ambient temperature and humidity, to cover the maximum amount of time the field samples were to be in storage at the laboratory. Table 4 provides a summary of the "field" fortified recovery results. The overall field fortification recoveries for the handwipes and dog hair were 96.9 and 98.8 percent, respectively. The only average recovery per fortification level which fell below 90% was the mid-level fortification average recovery for the handwipes. All handwipe sample residues reported in the range of this fortification level were corrected by Versar.

Table 4. Field Fortification Recoveries.

Fortification Level	Fortification Concentration (µg)	TCVP % Recovery	Average Recovery	Overall Average Recovery	Standard Deviation
HANDWIPES					
Low Level	10	101.9	97.4	96.9	12.1
		106			
		84.2			
Mid Level	500	72.1	88.6		
		94.8			
		98.9			
High Level	2000	96.7	104.6		
		107.9			
		109.3			
DOG HAIR					
Low Level	10	96.7	97.1	98.8	5.2
		96.4			
		98.1			
Mid Level	500	106.7	106.9		
		107.1			
		*			
High Level	8000	95.7	95.1		
		93.6			
		95.9			

* Sample lost during transit

Formulation: Each of the three test products were assayed before and after the study. The percent active ingredient (TCVP) found in each of the test products is reported below.

Storage Stability:

The "field" fortification samples discussed above were used to confirm storage stability while being stored and shipped between both the testing facility and the analytical laboratory. The results from these fortified samples support the stability of TCVP residues. However, sample collection dates and sample analysis dates were not provided in the study report. The length of time these

fortified samples remained in storage in comparison to the field samples can therefore not be determined.

To confirm the stability of the test product during the test, three additional units of each of the three test products were shipped to the test facility. These additional units were stored at ambient temperature and humidity until the last treatment day and then returned to the Hartz lab for analysis. The average percent active ingredient (TCVP) in the powdered test product prior to the study was 3.29%. The average percent active ingredient (TCVP) after the study was 3.11%. The average percent active ingredient (TCVP) in the aerosol test product prior to the study was 1.04%. The average percent active ingredient (TCVP) after the study was 1.11%. The average percent active ingredient (TCVP) in the pump spray test product prior to the study was 1.09%. The average percent active ingredient (TCVP) after the study was 1.11%.

II. RESULTS AND CALCULATIONS:

Versar corrected residue data for the handwipe samples that fell in the range of the mid-level field fortification samples for a recovery of 88.6%. The Registrant did not correct for field fortification recoveries because the overall field fortification recoveries were above 90%. None of the fur residue data were corrected.

Handwipe Residues:

EPA requested that the residue data be converted from µg (handwipe residue data units) and µg/g (fur residue data units) to µg/cm^2 and that regression analyses be run. Versar converted the handwipe data by first converting the surface stroking area of each dog from inches squared to cm^2 by multiplying each surface area by 6.452 cm^2/in^2. The amount of handwipe residue measured in µg was divided by the surface stroking area in cm^2 to get µg/cm^2. Residue data that fell below the level of detection (LOD) were treated as ½ LOD. The LOD (0.02 µg/ml) was converted to µg by multiplying the LOD by the dilution factor (31 ml) to get 0.62 µg (handwipe LOD). One half of the LOD (0.31 µg) for handwipes was converted to µg/cm^2 by dividing ½ the LOD by the dog-specific surface stroking area in cm^2. Therefore, the value used for ½ LOD for one handwipe sample may not be the same as another sample for a different dog.

Fur Residues:

Versar converted the fur residue data by first converting the total surface area shaved from inches squared to cm^2 by multiplying each surface area by 6.452. The amount of residue on the fur measured in µg/g was multiplied by the weight of the fur collected at each sampling interval and then this number was divided by the total surface area shaved

in cm^2 for each sampling interval to get $\mu g/cm^2$. Residue data that fell below the level of detection (LOD) were treated as ½ LOD. The LOD (0.02 µg/ml) was converted to µg by multiplying the LOD by the dilution factor (25 ml) to get 0.5 µg (dog fur LOD). One half of the LOD (0.25 µg) for handwipes was converted to $\mu g/cm^2$ by dividing ½ the LOD by the dog-specific surface area shaved in cm^2.

In order to run a dissipation regression analysis for the handwipe and fur residue data, the LOQ was converted to $\mu g/cm^2$. To calculate an LOQ which represented all of the handwipe residue samples, an overall average surface stroking area was calculated. The LOQ (0.04 µg/ml) was multiplied by the handwipe dilution factor of 31 ml and then divided by the overall surface stroking area (845.728 cm^2) to get 0.0015 $\mu g/cm^2$. To calculate an LOQ which represented all of the fur residue samples, an overall average surface area shaved was calculated. The LOQ (0.04 µg/ml) was multiplied by the animal fur dilution factor of 25 ml and then divided by the overall average surface area shaved (32.778 cm^2) to get 0.029 $\mu g/cm^2$. A value of ½ the LOQ was used for any residue value greater than the LOD, but less than the LOQ.

Hartz® 2 in 1® Flea and Tick Powder for Dogs

Tables 5a (fur residues) and 5b (handwipe residues) summarize the arithmetic means, standard deviations, coefficients of variance and natural logs for all residue replicate samples for each sampling interval. The average mean residual TCVP found on the dog fur peaked at 72.79 $\mu g/cm^2$ four hours after the treatment. The average mean dropped to 0.12 $\mu g/cm^2$ by DAT-32 (32 days after treatment). The coefficient of variation ranged from 42 to 86%. The average mean dislodgeable TCVP residue from the handwipe samples peaked at 0.312 $\mu g/cm^2$ four hours after treatment. The average mean dropped to 0.001 $\mu g/cm^2$ by the DAT-32. The coefficient of variation ranged from 28 to 104%.

Table 5c provides a summary of the percent TCVP dislodged by the hand after treatment with a Hartz powdered insecticide product. The highest percent dislodgeable TCVP was 1.49% which occurred at the 4 hour sampling interval for Applicator A. All of the dislodgeable TCVP percentages dropped to 0.01 or 0.00 by day 16.

Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs

Tables 6a (fur residues) and 6b (handwipe residues) summarize the arithmetic means, standard deviations, coefficients of variance and natural logs for all residue replicate samples for each sampling interval. The average mean residual TCVP found on the dog fur peaked at 73.17 $\mu g/cm^2$ four hours after the treatment. The average mean dropped to 0.28 $\mu g/cm^2$ by DAT-32. The coefficient of variation ranged from 34 to 105%. The average mean dislodgeable TCVP residue from the handwipe samples peaked at 1.58 $\mu g/cm^2$ four hours after treatment. The average mean dropped to 0.001 $\mu g/cm^2$ by DAT-32. The coefficient of variation ranged from 21 to 121%.

Table 6c provides a summary of the percent TCVP dislodgeable by hand after treatment with a Hartz aerosol spray insecticide product. The highest percent TCVP dislodgeable was 4.35% which occurred at the 4 hour sampling interval for Applicator B. All of the TCVP dislodgeable percentages dropped to zero by DAT-32. One of the dogs expired between the day 16 and day 32 sampling interval. The death was unrelated to the study.

Control Pet Care System® Flea and Tick Repellent Spray for Dogs

Tables 7a (fur residues) and 7b (handwipe residues) summarize the arithmetic means, standard deviations, coefficients of variance and natural logs for all residue replicate samples for each sampling interval. The average mean residual TCVP found on the dog fur peaked at 49.30 $\mu g/cm^2$ four hours after the treatment. The average mean dropped to 0.27 $\mu g/cm^2$ by DAT-32. The coefficient of variation ranged from 28 to 150%. The average mean dislodgeable TCVP residue from the handwipe samples peaked at 2.01 $\mu g/cm^2$ four hours after treatment. The average mean dropped to 0.001 $\mu g/cm^2$ by DAT-32. The coefficient of variation ranged from 30 to 90%.

Table 7c provides a summary of the percent TCVP dislodgeable by hand after treatment with a Hartz pump spray insecticide product. The highest percent TCVP dislodgeable was 11.11% which occurred at the 4 hour sampling interval for Applicator A. All of the TCVP dislodgeable percentages dropped to 0.01 or 0.00 by day 16.

III DISCUSSION

A. LIMITATIONS OF THE STUDY:

A specific compliance checklist for this type of study is not available. However, This study met most of the Series 875.2100 Guidelines (i.e., dislodgeable foliar residues on agricultural crops and quality assurance) (see Appendix A). The following issues of concern are noted:

- Fortification samples were spiked in the Hartz laboratory and then shipped to the testing facility. They were not fortified in the field. However, these samples served to support the stability TCVP in the matrix (handwipe or dog fur).
- There was no information about the test site in the study report.
- Sample collection dates and sample analysis dates were not provided in the study report to verify storage stability claims.
- Weather data were not provided in the study report.
- The product labels allow for multiple applications of the test product a few days apart. In this study, only one treatment was made to each dog.
- The Registrant reported that laboratory fortified samples were used concurrently with sample analyses. The recovery results for these laboratory fortified samples were not provided in the study report.

B. CONCLUSIONS:

EPA requested that Versar conduct linear regressions on the TCVP residues found on the dog fur after treatment using one of the three test products and on the dislodgeable TCVP residues found on the hand after treatment using one of the three test products (see Appendix A). The residue values were corrected, as needed, and converted to $\mu g/cm^2$. A value of ½ the LOQ was used for residue values greater than LOD, but less than the LOQ. Linear regressions were conducted using the natural logarithm of dislodgeable residue values processed by Microsoft's® Excel 2000.

Table 8 provides a summary of the regression analyses run for TCVP residues on dog fur after treatment with one of three test products. The half-lives for all three products ranged from 3.42 days (pump product) to 3.98 days (aerosol product). Table 9 provides a summary of the regression analyses run for dislodgeable TCVP residues found on the hand after treatment with one of three test products. The half-lives ranged from 2.81 days (aerosol product) to 3.52 days

(powder product). The pump product's R Square values were the lowest for both the fur residue and the dislodgeable hand residues (0.665 and 0.790. respectively).

Versar examined data variability as part of the linear regression analyses. The range of coefficients of variation for the regressions are summarized in Tables 8 and 9.

Table 5a. Residual TCVP on Dog Fur After Application with a Hartz Powdered Insecticide Product

Sampling Interval (Days after treatment)	Residue Level (µg/cm²)					Statistical summary of Residue Levels			
	Applicator A	Applicator B	Applicator C	Applicator D	Applicator E	Arithmetic Mean (µg/cm²)	Standard Deviation (µg/cm²)	Coefficient of Variation (%)	Natural Log of Mean (µg/cm²)
0.167	27.749	31.274	77.409	178.852	48.659	72.788	62.460	85.811	4.288
1	21.416	11.501	92.354	61.100	33.371	43.948	32.824	74.689	3.783
2	14.287	18.021	72.212	68.900	24.361	39.556	28.551	72.178	3.678
4	11.039	12.413	28.638	21.245	14.351	17.537	7.342	41.867	2.864
8	6.164	3.990	10.224	9.607	3.549	6.707	3.100	46.216	1.903
16	1.113	2.051	2.643	6.397	4.851	3.411	2.163	63.410	1.227
32	0.068	0.166	0.060	0.075	0.217	0.117	0.071	60.260	-2.145

Table 5b. Dislodgeable Residue Data for TCVP onto the Hand Using Handwipes After Application with a Hartz Powdered Insecticide Product

Sampling Interval (Days after treatment)	Dislodgeable Residue Level (µg/cm²)					Statistical summary of Dislodgeable Residue Levels			
	Applicator A	Applicator B	Applicator C	Applicator D	Applicator E	Arithmetic Mean (µg/cm²)	Standard Deviation (µg/cm²)	Coefficient of Variation (%)	Natural Log of Mean (µg/cm²)
0.167	0.413	0.224	0.395	0.299	0.230	0.312	0.089	28.504	-1.165
1	0.226	0.328	0.468	0.199	0.239	0.292	0.110	37.552	-1.231
2	0.186	0.432	0.133	0.180	0.217	0.230	0.117	50.976	-1.472
4	0.157	0.071	0.081	0.109	0.052	0.094	0.041	43.668	-2.366
8	0.045	0.035	0.013	0.039	0.015	0.029	0.015	49.891	-3.537
16	0.004	0.004	0.008	0.008	0.003	0.005	0.002	44.650	-5.254
32	0.001	0.00035 (1/2LOD)	0.00037 (1/2LOD)	0.00038 (1/2LOD)	0.003	0.001	0.001	104.013	-6.874

½ LOD which appears in the table is 0.31 µg divided by a dog specific surface stroking area..

Table 5c. Percent TCVP Dislodgeable by Hand After Treatment with a Hartz Powdered Insecticide Product

Applicator	Dog ID#		4 Hours	Day 1	Day 2	Day 4	Day 8	Day 16	Day 32
A	317	dislodgeable TCVP (µg)	320.43	175	144.00	122.00	34.70	3.06	0.96
		% TCVP dislodgeable	**1.49**	**0.81**	**0.67**	**0.57**	**0.16**	**0.01**	**0.00**
B	271	dislodgeable TCVP (µg)	197.2	288.94	380.36	62.60	30.40	3.34	ND
		% TCVP dislodgeable	**0.72**	**1.05**	**1.38**	**0.23**	**0.11**	**0.01**	**0.00**
C	267	dislodgeable TCVP (µg)	334.09	396.16	113.00	68.40	10.80	6.65	ND
		% TCVP dislodgeable	**0.51**	**0.6**	**0.17**	**0.10**	**0.02**	**0.01**	**0.00**
D	285	dislodgeable TCVP (µg)	241	161.00	145.00	87.90	31.30	6.17	ND
		% TCVP dislodgeable	**0.17**	**0.11**	**0.10**	**0.06**	**0.02**	**0.00**	**0.00**
E	260	dislodgeable TCVP (µg)	193.00	200.00	182.00	43.20	12.30	2.44	2.38
		% TCVP dislodgeable	**0.47**	**0.49**	**0.45**	**0.11**	**0.03**	**0.01**	**0.01**

Table 6a. Residual TCVP on Dog Fur After Application with a Hartz Aerosol Insecticide Product

Sampling Interval (Days after treatment)	Residue Level (µg/cm²)					Statistical Summary of Residue Levels			
	Applicator A	Applicator B	Applicator C	Applicator D	Applicator E	Arithmetic Mean (µg/cm²)	Standard Deviation (µg/cm²)	Coefficient of Variation (%)	Natural Log of Mean (µg/cm²)
0.167	65.969	44.767	56.254	98.861	99.987	73.167	25.119	34.331	4.293
1	16.167	47.934	35.420	32.460	175.600	61.516	64.771	105.292	4.119
2	10.481	19.110	24.603	60.402	46.237	32.167	20.574	63.960	3.471
4	6.935	10.416	8.946	14.009	19.771	12.016	5.047	42.007	2.486
8	1.527	3.559	8.000	9.303	10.415	6.561	3.834	58.438	1.881
16	1.241	0.589	3.562	3.283	1.517	2.038	1.311	64.330	0.712
32	0.080	0.451	0.135	0.442	NA	0.277	0.197	71.279	-1.285

NA - Dog expired between days 16 and 32.

Table 6b. Dislodgeable Residue Data for TCVP onto the Hand Using Handwipes After Application with a Hartz Aerosol Insecticide Product

Sampling Interval (Days after treatment)	Dislodgeable Residue Level (µg/cm²)					Statistical Summary of Dislodgeable Residue Levels			
	Applicator A	Applicator B	Applicator C	Applicator D	Applicator E	Arithmetic Mean (µg/cm²)	Standard Deviation (µg/cm²)	Coefficient of Variation (%)	Natural Log of Mean (µg/cm²)
0.167	1.603	1.947	1.750	1.559	1.061	1.584	0.329	20.795	0.460
1	0.999	1.212	0.902	1.168	0.687	0.993	0.212	21.385	-0.007
2	0.827	1.100	1.506	0.377	0.405	0.843	0.478	56.744	-0.171
4	0.177	0.373	0.341	0.121	0.138	0.230	0.118	51.295	-1.470
8	0.026	0.038	0.032	0.041	0.019	0.031	0.009	28.982	-3.469
16	0.003	0.003	0.005	0.009	0.003	0.005	0.002	52.471	-5.413
32	0.00039 (½ LOD)	0.00038 (½ LOD)	0.001	0.004	NA	0.001	0.002	121.159	-6.562

NA - Dog expired between days 16 and 32.

½ LOD which appears in the table is 0.31 µg divided by a dog specific surface stroking area..

Table 6c. Percent TCVP Dislodgeable by Hand After Treatment with a Hartz Aerosol Insecticide Product

Applicator	Dog ID#		4 Hours	Day 1	Day 2	Day 4	Day 8	Day 16	Day 32
A	315	dislodgeable TCVP (µg)	1277.00	795.71	659.14	141.00	20.50	2.46	ND
		% TCVP dislogeable	**2.43**	**1.51**	**1.25**	**0.27**	**0.04**	**0.00**	**0.00**
B	304	dislodgeable TCVP (µg)	1605.00	998.87	906.32	307	31.6	2.51	ND
		% TCVP dislogeable	**4.35**	**2.71**	**2.46**	**0.83**	**0.09**	**0.01**	**0.00**
C	279	dislodgeable TCVP (µg)	1482.00	764.11	1275.4	288.94	27.30	3.82	0.79
		% TCVP dislogeable	**3.11**	**1.6**	**2.68**	**0.61**	**0.06**	**0.01**	**0.00**
D	262	dislodgeable TCVP (µg)	1275.00	954.85	308.13	99.20	33.30	6.95	3.23
		% TCVP dislogeable	**1.58**	**1.18**	**0.38**	**0.12**	**0.04**	**0.01**	**0.00**
E	283	dislodgeable TCVP (µg)	981.94	635.44	374.72	128.00	17.40	2.92	NA
		% TCVP dislodgeable	**1.06**	**0.69**	**0.4**	**0.14**	**0.02**	**0.00**	**NA**

Table 7a. Residual TCVP on Dog Fur After Application with a Hartz Pump Spray Insecticide Product

Sampling Interval (Days after treatment)	Residue Level (µg/cm²)					Statistical summary of Residue Levels			
	Applicator A	Applicator B	Applicator C	Applicator D	Applicator E	Arithmetic Mean (µg/cm²)	Standard Deviation (µg/cm²)	Coefficient of Variation (%)	Natural Log of Mean (µg/cm²)
0.167	21.910	47.631	54.840	92.636	29.492	49.302	27.632	56.047	3.898
1	16.543	61.338	14.887	50.930	12.272	31.194	23.113	74.094	3.440
2	23.839	9.526	10.432	14.136	11.044	13.795	5.876	42.591	2.624
4	3.181	23.767	4.157	11.974	1.581	8.932	9.210	103.108	2.190
8	0.175	2.065	3.574	1.523	0.216	1.511	1.416	93.760	0.413
16	0.031	3.843	2.781	1.193	0.009	1.572	1.701	108.261	0.452
32	0.0039 (1/2LOD)	0.872	0.044	0.163	0.017	0.271	0.406	150.063	-1.306

LOD = 0.015 µg/cm² however, the ½ LOD which appears in the table is 0.31 µg divided by a dog-specific surface stroking area.

Table 7b. Dislodgeable Residue Data for TCVP onto the Hand Using Handwipes After Application with a Hartz Pump Spray Insecticide Product

Sampling Interval (Days after treatment)	Dislodgeable Residue Level (µg/cm²)					Statistical summary of Dislodgeable Residue Levels			
	Applicator A	Applicator B	Applicator C	Applicator D	Applicator E	Arithmetic Mean (µg/cm²)	Standard Deviation (µg/cm²)	Coefficient of Variation (%)	Natural Log of Mean (µg/cm²)
0.167	2.433	1.348	1.416	3.595	1.267	2.012	1.004	49.924	0.699
1	0.977	0.837	0.378	1.188	0.960	0.868	0.302	34.776	-0.142
2	0.399	0.498	0.202	0.465	0.364	0.385	0.116	29.967	-0.954
4	0.050	0.170	0.070	0.150	0.065	0.101	0.055	54.500	-2.292
8	0.009	0.048	0.015	0.032	0.009	0.022	0.017	76.092	-3.802
16	0.001	0.005	0.00038 (½ LOD)	0.004	0.002	0.002	0.002	79.878	-6.031
32	0.00038 (½ LOD)	0.00030 (½ LOD)	0.0020	0.00038 (½ LOD)	0.002	0.001	0.001	90.173	-6.943

½ LOD which appears in the table is 0.31 µg divided by a dog-specific surface stroking area.

Table 7c. Percent TCVP Dislodgeable by Hand After Treatment with a Hartz Pump Spray Insecticide Product

Applicator	Dog ID#		4 Hours	Day 1	Day 2	Day 4	Day 8	Day 16	Day 32
A	313	dislodgeable TCVP (µg)	1990.00	799.1	326.19	40.50	7.26	0.54	ND
		% TCVP dislodgeable	**11.11**	**4.46**	**1.82**	**0.23**	**0.04**	**0.00**	**0.00**
B	258	dislodgeable TCVP (µg)	1400.00	869.07	516.93	177.00	49.60	4.82	ND
		% TCVP dislogeable	**2.83**	**1.76**	**1.04**	**0.36**	**0.10**	**0.01**	**0.00**
C	306	dislodgeable TCVP (µg)	1151.24	307	164.00	57.00	11.80	ND	1.27
		% TCVP dislogeable	**2.58**	**0.69**	**0.37**	**0.13**	**0.03**	**0.00**	**0.00**
D	223	dislodgeable TCVP (µg)	2940.00	971.78	380.36	123.00	25.80	3.29	ND
		% TCVP dislogeable	**3.88**	**1.28**	**0.5**	**0.16**	**0.03**	**0.00**	**0.00**
E	257	dislodgeable TCVP (µg)	1062.08	804.74	304.74	54.60	7.46	1.94	1.85
		% TCVP dislodgeable	**4.3**	**3.25**	**1.23**	**0.22**	**0.03**	**0.01**	**0.01**

Table 8. Summary of Regressions for TCVP Residues on Dog Fur After Treatment with One of Three Test Products.

Test Product	Half-Life (days)	R Square.	Range of Coefficient of Variation (%)
Hartz® 2 in 1® Flea and Tick Powder for Dogs	3.69	0.907	42 to 86
Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs	3.98	0.839	34 to 105
Control Pet Care System® Flea and Tick Repellent Spray for Dogs	3.42	0.665	43 to 168

Table 9. Summary of Regressions for Dislodgeable TCVP Residues on Hand After Treatment with One of Three Test Products.

Test Product	Half-Life (days)	R Square	Range of Coefficient of Variation (%)
Hartz® 2 in 1® Flea and Tick Powder for Dogs	3.52	0.908	28 to 104
Hartz® 2 in 1® Fast Acting Flea and Tick Spray for Dogs	2.81	0.859	21 to 122
Control Pet Care System® Flea and Tick Repellent Spray for Dogs	2.86	0.79	30 to 90

Name:
Evaluator
Occupational Exposure Assessment Section

Date

Name:
Peer Reviewer
Occupational Exposure Assessment Section

Date

Name:
Head.
Occupational Exposure Assessment Section

Date

APPENDIX A

Compliance Checklist for "Determination of the Dislodgeability of TCVP from the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol"

Compliance Checklist for "Determination of the Dislodgeability of TCVP From the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol"

The following is an OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Part B: Postapplication Exposure Monitoring Test Guidelines, Dislodgeable Foliar Residue Dissipation: Agricultural (Guideline 875.2100) and Part C: QA/QC checklist. Not all of the items on this check list apply to this type of study. However, the itemized checklist below describes compliance with the major technical aspects of Series 875 Part B and Part C Guidelines, and is based on the "Checklist for Residue Dissipation Data" used for study reviews by the U.S. EPA/OPP/HED.

- *Typical end use products of the active ingredient used.* This criterion was met.

- *Dislodgeable residue (DR) data should be collected from at least three geographically distinct locations for each formulation and crop type.* This criterion was <u>not</u> met. This study took place at only one location. However, due to the nature of the study, the Registrant claimed that geographical location would have no impact on the study.

- *The production of metabolites, breakdown products, or the presence of contaminants of concern, should be considered in the study design on a case-by-case basis.* This criterion was met. The target analyte for this study was tetrachlorvinphos (TCVP).

- *Site(s) treated should be representative of reasonable worst-case climatic conditions expected in intended use areas.* It is unknown whether this criterion was met. According to the Registrant, factors such as season and location are not relevant to characterizing the dislodgeability in this type of study and thus they were not included in this study design.

- *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.* These criteria were mostly met. Each test product was applied using the application method and application rate specified on the product labels. However, the product label specifies that additional treatments can be made a few days apart. Only one treatment was applied in this study.

- *Applications occurred at time of season that the end-use product is normally applied to achieve intended pest control.* This criterion was met. Applications of these test products can be made anytime of the year.

- *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion is not applicable. Only one treatment was done. The product label does allow for multiple treatments "a few days apart."

- *Sampling should be sufficient to cover three half-lives and establish a dissipation curve.* This criterion was met. Samples were collected prior to and 4 hours following the treatment, and at 1, 2, 4, 8, 16, and 32 days after the treatment. The TCVP residue half-lives ranged from 2.81 to 3.98 days.

- *Meteorological conditions including temperature, wind speed, daily rainfall, and humidity should be provided for the duration of the study.* This criterion was <u>not</u> met. The study report did not provide any temperature or relative humidity data. These data are probably not relevant to this type of study.

- *Reported residue dissipation data in conjunction with toxicity data must be sufficient to support the determination of a reentry interval.* This study did not provide dissipation data nor toxicity data for these test products. Versar analyzed the dissipation of the TCVP residues.

- *Residue storage stability, method efficiency (residue recovery), and limit of quantitation (LOQ) should be provided.* These criteria were mostly met. A storage stability study was performed before this study was initiated. Laboratory and field fortification samples were used to support method efficiency. However, the laboratory fortification data were not provided in the study report. The LOQ was reported to be 0.04 µg/ml. The LOD was reported to be 0.02 µg/ml.

- *Triplicate, randomly collected samples should be collected at each sampling interval.* This criterion was met. Five replicate samples were collected for each matrix at each sampling interval.

- *Control and baseline foliar or soil samples should be collected.* This criterion was met. Baseline samples were collected prior to the application of the test product on each dog.

APPENDIX B

Versar's Regression Analysis for Determination of the dislodgeability of Tetrachlorvinphos (TCVP) From the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol.