Versar inc.

MEMORANDUM

TO: Zaida Figueroa

cc: 110082.5000.001.01
Shanna Recore

FROM: Laura Guziak/Kelly McAloon

DATE: April 29, 2004

SUBJECT: Review of "*Measurement of Air Concentration and Deposition on Cotton Dosimeters of Metofluthrin Generated by a Personal Outdoor Insect Repellant Device in an Outdoor Environment*" (TAF 5-1-6; MRID 464020-04)

This report reviews a study entitled "*Measurement of Air Concentration and Deposition on Cotton Dosimeters of Metofluthrin Generated by a Personal Outdoor Insect Repellant Device in an Outdoor Environment,*" submitted by S.C. Johnson & Son, Inc. The study measured surface and air residues in an outdoor residential setting, using dosimeters, air sampling tubes and wipes. Versar used the following guidelines in the review of the Study Report: 1) OPPTS Series 875 Part B, Guideline 875.2400: Dermal Exposure, Postapplication, 2) OPPTS Series 875 Part B, Guideline 875.2500: Inhalation Exposure, Postapplication, and 3) Part C Guidelines.

Reviewer: Laura Guziak/Kelly McAloon **Date** April 29, 2005

STUDY TYPE: Outdoor Residential Dosimetry and Personal Air Concentration Study for a Personal Insect Repellent Device using Patch Dosimetry and Personal Air Sampling

TEST MATERIAL: Metofluthrin (SumiOne™) is an insecticide, which coats the cartridge insert of "NORM 1", a personal outdoor mosquito repellent device. The target weight of metofluthrin in the NORM 1 device is 15 to 20 mg.

SYNONYMS: Metofluthrin

CITATION:

Author:	Sami Selim, Ph.D.
Study Completion Date:	November 4, 2004
Title:	*Measurement of Air Concentration and Deposition on Cotton Dosimeters of Metofluthrin Generated by a Personal Outdoor Insect Repellent Device in an Outdoor Environment*
Field Laboratory:	2095 W. Spruce Ave Fresno, CA 93711, USA
Analytical Laboratory:	Golden Pacific Laboratories, LLC (GPL) 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722-6420, USA
Project Identification:	040166
MRID:	46402004

SPONSOR: S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403-2236, USA

EXECUTIVE SUMMARY:

The purpose of this study was to determine the air concentration of metofluthrin at two different locations (two different heights, adult and child breathing zones) following the use of a personal mosquito repellent device (Norm-1) and to determine the deposition of metofluthrin onto dosimeters and the potential dermal exposure from touching the Norm-1 device or potential incidental ingestion of residues by children using wipe samples. Three separate runs were conducted in an outdoor residential patio location during the evening hours of early fall 2004 in California to simulate expected use conditions. Temperatures were recorded as ranging from 65□C to 87□C and were monitored in addition to humidity and wind speed.

Two manikins were utilized as the test subjects. One of the manikins represented an adult and the other represented a child. Their respective breathing zones were 1.6 m and 1.0 m. A distance of 0.4 m separated the two manikins. The adult manikin wore the Norm-1 device secured on its waist. The device was operated for a period of six hours for each of the runs. Air samples were collected by placing air sampling OVS tubes connected to air sampling pumps in the breathing zones of the two manikins. The sampling tubes were positioned with the tubes opening downwards and were connected to pre-calibrated pumps that operated at an airflow rate of approximately 2 L/min. The tubes were replaced with fresh tubes midway through the exposure period, such that samples were collected at 0-3 and 3-6 hours. The adult manikin was outfitted with a cotton long john dosimeter for each run. After each six hour exposure period, seven patches were cut from predetermined locations on the dosimeter to be analyzed for residues of metofluthrin. The device itself was wiped with gauze wetted with dioctyl sodium sulfosuccinate (DSS)

to estimate potential incidental ingestion and isopropyl alcohol (IPA) to estimate potential incidental dermal exposure.
No residues in the air sampling tubes above the LOQ of 42.8 ng/sample were detected in any of the three runs for 1-3 and 3-6 hours for both the adult and child manikins. Versar used ½ the LOQ (21.4 ng) as the average OVS tube sample residue for the three runs. Versar calculated the total volume of air that was pumped through each sample tube in cubic meters for each 3 hour duration as 0.36 m^3. This value was used to calculate the concentration of metofluthrin in the air by dividing the inhalation residue by the total air volume. Potential inhalation exposure was calculated by Versar using the EPA estimated child inhalation rate of 0.7 m^3/hr and adult inhalation rate of 1.6 m^3/hr for light to moderate activity (EPA SAC Policy No. 11 dated 2/22/01). Potential inhalation exposures were determined to be 0.042 µg/hr for children and 0.095 µg/hr for adults. Neither Versar nor the Registrant corrected the residues for recovery efficiencies, which were >90%.

Only four of the dosimeter samples had residues, which ranged from 0.536 µg/sample to 1.43 µg/sample. The remaining samples were either below the LOQ or were not detected. For residues <LOQ, Versar assumed those values were equal to ½ the LOQ. Versar corrected the quantifiable dosimeter residue data for field fortification recoveries less then 90%. The average corrected residues for the dosimeter samples ranged from 0.0107 µg/cm^2 to 0.046 µg/cm^2 (using a patch size of 25 cm^2).

All of the DSS wipes samples had measured residues <LOQ. Using ½ the LOQ when residues were <LOQ, Versar calculated the average DSS wipe sample residue for the three runs to be 0.54 µg/sample. The IPA wipes samples had measured residues ranging from 1.52 µg/sample to 1.86 µg/sample over the course of three runs, with an average residue of 1.70 µg/sample. Neither Versar nor the Registrant corrected the residues for average recovery efficiencies, which were >90%. The overall averages for the DSS and IPA wipes in µg/cm^2 (wipe size = 16 cm^2) were 0.03 µg/cm^2 for the DSS wipes and 0.11 µg/cm^2 for the IPA wipes.

Versar reviewed the Study Report for compliance with respect to OPPTS Test Guidelines Series 875, Part B, Guideline 875.2400 (postapplication dermal exposure) and 875.2500 (postapplication inhalation exposure). Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the guidelines. However, certain issues of concern were noted:

- $ No protocol was submitted with the Study Report.
- $ The Study Report stated that all data collection and study conduct were performed in the spirit of GLP, however, the study was not performed according to the GLP Regulations currently in effect.
- $ Only three replicates were taken of the DSS and IPA wipe sample and only 6 replicates for the OVS tubes compared to the required minimum of 15 replicates per activity.
- $ The monitoring period was not of sufficient duration to result in reasonable detectability on dosimeters and baseline samples were not collected prior to the study.
- $ The study was performed on stationary manikins which may have provided different results than test subjects that would be able to perform mobile outdoor residential activities.
- $ Data was not corrected for field fortified recoveries of less than 90%.
- $ A storage stability study was not conducted.
- $ A trapping efficiency test was not conducted.
- $ Air flow rates were not provided in the Study Report.
- $ No information was provided regarding extraction method, method validation, or instrument performance and calibration for the analytical phase.
- $ The Study Report did not state how many days the samples were stored prior to analysis.
- $ No information was provided on the field blanks regarding the duration of exposure for each matrix or the method of storage to avoid cross-contamination.
- $ It was not noted if the field fortified samples were exposed downwind of the application site.
- $ Dermal residues were not reported on a surface area basis (i.e., normalized on patch sample surface area; µg/cm^2 or mg/cm^2). Residues were reported on a µg/sample basis.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. However, the GLP statement notes that the study was not performed according to the US EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160). The data collection and study conduct were said to have been performed in the spirit of the GLP, which included following GPL (Golden Pacific Laboratories, LLC)'s Standard Operating Procedures.

GUIDELINE OR PROTOCOL FOLLOWED: A study protocol was not provided in the Study Report. The study was reviewed using OPPTS Test Guidelines Series 875, Part B, Guideline 875.2400 (postapplication dermal exposure) and 875.2500 (postapplication inhalation exposure).

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

Formulation:	Norm-1 is a personal insect repellent device that contains a cartridge insert coated with up to 20 mg of the active ingredient metofluthrin (SumiOne™). A certificate of analysis with an expiration date was not provided.
Lot/Batch #:	508D2 (test substance batch number) 1CM24 (reference substance lot number)
Purity:	The purity of the metofluthrin reference standard was verified at 95.74%. No expiration date was provided.
CAS #(s):	240494-70-6

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

A product label for Norm 1 was not provided in the Study Report. However, it was provided in an accompanying document (MRID 464020-05: "Metofluthrin: Non-Dietary (Residential) Risk Assessment and Personal Outdoor Insect Repellent Device" October 25, 2004; J. Driver and J. Ross). The test product used in this study is formulated the same as what is described on the Norm-1 label (EPA Reg. No. 4822-)

B. STUDY DESIGN

No study protocol was provided and no amendments or deviations were noted.

1. Exposure Scenario

Samples were taken to determine the air concentrations and residue deposition of metofluthrin generated as a result of the use of a personal mosquito repellent device. The study was performed outdoors to simulate actual use conditions and at night to minimize photodegradation.

2. Number and Type of Individuals Monitored and Sites:

Two manikins were monitored at one site on three separate nights. One of the manikins simulated an adult, which wore the Norm-1 device, and the other manikin simulated a child standing next to the adult. The testing site was an outdoor patio at a private residence in Fresno, California. The patio was enclosed on three sides with a ceiling overhead. The fourth side was open to the outdoor environment.

3. Meteorology:

The studies were performed at night to minimize the effect of sunlight and possible photodecomposition of the active ingredient. The temperature and humidity were monitored every 30 minutes at the field site. The direction and wind speed was also monitored. Table 1 provides meteorological data pertinent to the study. No wind was detected on any of the three testing days.

Table 1. Meteorological Data for All Test Runs During Application Events

Test Day	Time	Temperature (°F)	Humidity (%)	Light Conditions
Day 1	5:43 p.m.	84.5	31.6	Shaded
	6:40 p.m.	81.4	35.9	Shaded (Sun at horizon)
	7:45 p.m.	75.6	44.2	Sundown (Dark)
	8:42 p.m.	73.7	44.9	Sundown (Dark)
	9:42 p.m.	71.4	49.9	Sundown (Dark)
	10:47 p.m.	68.6	55.7	Sundown (Dark)
	11:40 p.m.	65.9	61.5	Sundown (Dark)
Day 2	6:10 p.m.	84.8	35.5	Shaded
	6:57 p.m.	81	39.6	Sun at horizon
	7:58 p.m.	77.9	42.2	Sundown (Dark)
	9:02 p.m.	72.9	47.9	Dark
	10:02 p.m.	69.8	55.9	Dark
	10:59 p.m.	67.3	73.5	Dark
	11:50 p.m.	66	73.4	Dark
Day 3	6:12 p.m.	87	41.8	Shaded
	7:07 p.m.	81.7	46.7	Sun at horizon
	8:01 p.m.	77.7	53.7	Sundown (Dark)
	9:12 p.m.	76.3	58.3	Dark
	10:02 p.m.	73.2	56.8	Dark
	11:03 p.m.	71.1	69.5	Dark
	12:06 p.m.	71.9	65.7	Dark
	12:32 p.m.	71.1	65.6	Dark

4. Application Rates and Regimes:

Application Rate(s): An application rate was not provided in the Study Report. According to MRID 464020-05 ("Metofluthrin: Non-Dietary (Residential) Risk Assessment and Personal Outdoor

Insect Repellent Device" October 25, 2004; J. Driver and J. Ross), during a 12-hour period of use, the manufacturer S.C. Johnson & Son, Inc., has estimated the emission rate of metofluthrin from the Norm-1 device as ranging from 0.4 to 0.7 mg/hr.

Application Regime: The Norm-1 device was secured at the waist of the adult manikin and the device was started. Each of the three runs lasted six hours.

5. Replicates:

Three runs were conducted over three separate nights for six hour periods. The label states that the device can provide up to 12 hours of continuous protection. For each run, the following air sample, dosimeter, DSS, and IPA wipe samples were collected:

Air Samples: Two samples (1-3 hrs. and 3-6 hrs.) were taken for both the adult and child manikin during all three runs for a total of six adult samples and six child samples. The air sampling tubes were located at a height of 1.6 m for the adult and 1.0 m for the child manikin.

Dosimeters: Seven samples from the adult manikins were cut from the dosimeters on each of the three nights the study was conducted for a total of three replicates for each location and twenty-one total dosimeter samples.

DSS and IPA Wipes: Two DSS and IPA wipes were used per wipe sample, for a total of three DSS wipe samples and three IPA wipe samples. The repellent device was first wiped (twice) with a wipe moistened with DSS and then (twice) with a wipe moistened with IPA.

7. Exposure monitoring methodology:

The Norm-1 device was secured at the waist of the adult manikin. The child manikin was placed at a distance of 0.4 m from the adult manikin.

Inhalation: Potential inhalation exposure was monitored by attaching air sampling tubes to air sampling pumps placed at the breathing zones of the two manikins. Each absorbent OVS, XAD-2 tube (SKC, Inc.) was attached to an individual pre-calibrated AirChek 2000 pump. The airflow rate was approximately 2 L/min. The sampling tubes were positioned with the tubes pointing downwards.

Air samples were collected continuously for 1-3 and 3-6 hours. After the first three hours, the air sampling tubes were collected and replaced with new air sampling tubes for the remaining three hours. At the end of sampling, each tube was capped and moved to freezer storage at less than -5°C within less than one hour of collection.

Dosimeters: Potential dermal exposure was monitored by dressing the adult manikin in cotton long johns (dosimeters) manufactured by Wearguard and cutting seven "patch" samples at the end of each six hour exposure period. The "patches" cut from the dosimeters were 5 cm x 5 cm. Samples were taken from the following locations: lower right leg, upper right leg, lower torso, upper torso, chest, lower right arm, and upper left leg. Within one hour of collection, the samples were placed in pre-labeled amber glass jars and moved to freezer storage at less than -5°C.

DSS and IPA Wipes: Potential incidental ingestion exposures to children associated with a presumed episodic incident of direct mouthing of the external surface of the device was monitored based on saliva simulated (dioctyl sodium sulfosuccinate) DSS wipes. Potential incidental dermal exposures from touching the external surface of the Norm-1 device was monitored with surface IPA (isopropyl alcohol) gauze wipe samples. After each six hour exposure period, the NORM-1 device was first wiped twice with a 4 x 4 cm Kendall Curity Gauze wipe moistened with DSS. Then the device was wiped twice with a 4 x 4 cm wipe moistened with IPA. Both wipes of the same solvent were placed in the same pre-labeled glass jars and moved to freezer storage at less than -5°C within one hour of collection.

After collection, all of the samples were stored in a freezer. Samples were transported from the field location to Golden Pacific Laboratories in Fresno, California the following day. Sample analysis for the study was initiated on September 13, 2004 and was terminated on September 20, 2004. The Study Report did not state how many days the samples were stored prior to analysis.

8. Analytical Methodology:

The detection method was GC/ECD. No information was provided regarding extraction method, method validation, or instrument performance and calibration for the analytical phase. The Study Report only states that analysis of all samples was performed by GPL. Statistical analysis methods included the calculation of means of replicate analyses, the standard deviations, and the coefficients of variation where appropriate. Quadratic regression was used in the generation of calibration curves. All data collection was archived with the study file and the analytical phase of the study was recorded as per GLP requirements.

No information was provided on the determination of the limit of quantification (LOQ) in the Study Report. The LOQs provided were 42.8 ng/sample, 0.535 µg/sample, and 1.07 µg/sample for the air sampling tubes, dosimeters, and wipes, respectively.

9. Quality Control:

Lab Recovery: Laboratory fortification recovery samples were prepared and analyzed prior to the start of the sample analysis to ensure the method was working properly. Fortification levels were 1x LOQ and 10x LOQ. Versar verified the recovery results provided in the Study Report. Versar calculated a different laboratory recovery for one of the wipe samples at the high fortification level than that reported in the Study Report. No raw data was provided to aid in the determination of this discrepancy. The overall average recoveries calculated by Versar for the OVS tubes, dosimeters, and wipes were 96.5%, 83.4%, and 86.5%, respectively. Table 2 provides a summary of the fortification recoveries for each matrix.

Table 2. Summary of Laboratory Fortified Samples Recoveries for All Matrices

Matrix	Fortification Level	Recoveries (%)	Average Recovery (%)	Overall Average Recovery (%)	Standard Deviation (%)
OVS Tubes	Low (1x LOQ)	114, 113, 104, 106, 88.1, 72.7	99.7	96.5	15
	High (10x LOQ)	89.7, 84.1	86.9		

Table 2. Summary of Laboratory Fortified Samples Recoveries for All Matrices					
Matrix	Fortification Level	Recoveries (%)	Average Recovery (%)	Overall Average Recovery (%)	Standard Deviation (%)
Dosimeters	Low (1x LOQ)	73.1, 72.1, 95.3, 90.5, 76.3, 81.7	81.5	83.4	10.1
	High (10x LOQ)	98.1, 80.0	89.1		
Wipes	Low (1x LOQ)	93.5, 103, 93.5, 76.2, 77.9, 80.7	87.4	86.5[c]	9.92
	High (10x LOQ)	76.8[a], 90.7	83.8[b]		

a Value reported in Study Report = 86.8%
b Value reported in Study Report = 88.8%
c Value reported in Study Report = 87.8%

Field blanks: Two unfortified control samples were collected for the air sampling tubes and dosimeters and three unfortified control samples were collected for the wipes. None of the laboratory or field control samples showed any residues above the LOQ. No information was provided regarding the duration of exposure of each matrix or the method of storage to avoid cross-contamination.

Field recovery: Field fortification samples were prepared for each of the three runs. Samples of air sampling tubes, dosimeters, and wipes were fortified in the field at two or three levels, ranging from 2x LOQ to 100x LOQ. Duplicate samples were utilized for the air sampling tubes and dosimeters, but not for the wipes. It was not noted if the field fortified samples were exposed downwind of the application site.

For field sampling tubes, air was drawn through each fortified field sample tube following the fortification for approximately three hours at approximately 2 L/min. After collection, the sample tubes were capped. Cotton dosimeters were fortified and allowed to "weather" for six hours. After the six hour weathering period, the samples were transferred to pre-labeled amber glass jars. The field fortifications were stored at less than -5°C, until transported to GPL for analysis. These samples were stored and analyzed with the test samples. Table 3 provides a summary of the field fortification results for each of the matrices as calculated by Versar using the values provided in the Study Report. Overall average field fortification recoveries were 108% for the OVS tubes, 79.4% for the dosimeters, and 106% for the wipes.

Table 3. Field Fortification Results				
Fortification Level	Recoveries (%)	Average Recovery (%)	Overall Average Recovery (%)	Standard Deviation (%)
OVS Tubes				
Low	109, 107, 118, 108, 109, 105	109	108	7.45
High	95.8, 124, 106, 104, 101, 113	107		
Dosimeter Samples				
Low	131, 12.3, 31.8, 106,	71.2	79.4	26.6

Table 3. Field Fortification Results				
Fortification Level	Recoveries (%)	Average Recovery (%)	Overall Average Recovery (%)	Standard Deviation (%)
	68.7, 84.4, 96.3, 56.4, 54.4			
Mid	76.1, 66.5, 86.4, 71.2, 73.5, 73.6	74.5		
High	122, 65.3, 70.7, 103, 82.8, 76.9, 113, 82.4, 100	90.7		
Wipes				
Low	126, 102, 103	110	106	12.5
High	112, 106, 87.7	102		

Storage Stability: Samples were stored for no more than eight days before analysis (experiment start date: 9/13/04 and sample analysis termination date: 9/20/04); however, no information was provided on the storage stability of the test substance.

10. Relevancy of Study to Proposed Use Pattern:
The study design and the proposed uses for this chemical are similar.

II. RESULTS AND CALCULATIONS:

A. Inhalation Residues:

Inhalation exposures were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined by the amount of metofluthrin found in the OVS tubes. The breathing zones of the adult and child manikins were 1.6 m and 1.0 m, respectively. The personal monitoring pumps were set at an airflow of 2.0 L/min. No residues in the air sampling tubes above the LOQ of 42.8 ng/sample were detected in any of the three runs for 1-3 and 3-6 hours for both the adult and child manikins.

Versar used ½ the LOQ (21.4 ng) as the average OVS tube sample residue for the three runs. Versar calculated the total volume of air that was pumped through each sample tube in cubic meters for each 3 hour duration as 0.36 m^3. This value was used to calculate the concentration of metofluthrin in the air by dividing the inhalation residue by the total air volume. Potential inhalation exposure was calculated by Versar using the EPA estimated child inhalation rate of 0.7 m^3/hr and adult inhalation rate of 1.6 m^3/hr for light to moderate activity (EPA SAC Policy No. 11 dated 2/22/01). Potential inhalation exposures were determined to be 0.042 µg/hr for children and 0.095 µg/hr for adults. Neither Versar nor the Registrant corrected the residues for recovery efficiencies, which were >90%. Versar's results are shown in Table 6.

B. Dosimeter Residues:

Only four of the dosimeter samples had residues, which ranged from 0.536 µg/sample to 1.43 µg/sample. The remaining samples were either below the LOQ or were not detected. For residues <LOQ, Versar assumed those values were equal to ½ the LOQ. Versar corrected the quantifiable dosimeter residue data for field fortification recoveries less then 90%. The average corrected residues for the dosimeter samples ranged from 0.0107 µg/cm^2 to

0.046 µg/cm^2 (using a patch size of 25 cm^2). The results are shown in Table 7.

C. Wipe Residues:

All of the DSS wipes samples had measured residues <LOQ. Using ½ the LOQ when residues were <LOQ, Versar calculated the average DSS wipe sample residue for the three runs to be 0.54 µg/sample. The IPA wipes samples had measured residues ranging from 1.52 µg/sample to 1.86 µg/sample over the course of three runs, with an average residue of 1.70 µg/sample. Neither Versar nor the Registrant corrected the residues for average recovery efficiencies, which were >90%. The overall averages for the DSS and IPA wipes in µg/cm^2 (wipe size = 16 cm^2) were 0.03 µg/cm^2 for the DSS wipes and 0.11 µg/cm^2 for the IPA wipes. These results are summarized in Table 8.

III DISCUSSION

A. CONCLUSIONS:

Metofluthrin residues resulting from the use of a personal mosquito repellent device were analyzed using dosimeters (dermal exposure), personal air sampling tubes (inhalation exposure), and wipes (incidental dermal and ingestion exposure). Residues of metofluthrin in OVS tubes, dosimeter samples, and DSS and IPA wipe samples were low. None of the OVS tubes contained residues above the LOQ of 42.8 ng/sample. The Registrant did not calculate potential inhalation exposure (µg/hr) in the Study Report. Only four of the dosimeter samples contained residues that were detectable and above the LOQ. The highest of these values was 0.08 µg/cm^2, according to Versar's calculations. All of the DSS wipe sample residues were below the LOQ. The IPA wipe samples all had measured residues just above the LOQ.

B. LIMITATIONS OF THE STUDY:

Versar reviewed the Study Report for compliance with respect to OPPTS Test Guidelines Series 875, Part B, Guideline 875.2400 (postapplication dermal exposure) and 875.2500 (postapplication inhalation exposure). Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the guidelines. However, certain issues of concern were noted:

- $ No protocol was submitted with the Study Report.
- $ The Study Report stated that all data collection and study conduct were performed in the spirit of GLP, however, the study was not performed according to the GLP Regulations currently in effect.
- $ Only three replicates were taken of the DSS and IPA wipe sample and only 6 replicates for the OVS tubes compared to the required minimum of 15 replicates per activity.
- $ The monitoring period was not of sufficient duration to result in reasonable detectability on dosimeters and baseline samples were not collected prior to the study.
- $ The study was performed on stationary manikins which may have provided different results than test subjects that would be able to perform mobile outdoor residential activities.
- $ Data was not corrected for field fortified recoveries of less than 90%.
- $ A storage stability study was not conducted.
- $ A trapping efficiency test was not conducted.
- $ Air flow rates were not provided in the Study Report.
- $ No information was provided regarding extraction method, method validation, or instrument performance and calibration for the analytical phase.
- $ The Study Report did not state how many days the samples were stored prior to analysis.
- $ No information was provided on the field blanks regarding the duration of exposure for each matrix or the method of storage to avoid cross-contamination.

$ It was not noted if the field fortified samples were exposed downwind of the application site.
$ Dermal residues were not reported on a surface area basis (i.e., normalized on patch sample surface area; µg/cm^2 or mg/cm^2). Residues were reported on a µg/sample basis.

Table 6. Summary of Residues of Metofluthrin in OVS Tubes

Sample Description	Inhalation Residue (ng)			Mean Residue (ng)	Flow Rate (L/min)	Duration (min)	Total Volume (m^3)[b]	Air Concentration (µg/m^3)[c]	Potential Inhalation Exposure (µg/hr)[d]
	Run 1	Run 2	Run 3						
Child, 1-3 hrs.	21.4[a]	21.4	21.4	21.4	2	180	0.36	0.059	0.0416
Adult, 1-3 hrs.	21.4	21.4	21.4	21.4					0.0951
Child, 3-6 hrs.	21.4	21.4	21.4	21.4					0.0416
Adult 3-6 hrs.	21.4	21.4	21.4	21.4					0.0951

a Residues were < LOQ of 42.8 ng/sample, therefore, ½ the LOQ was used for all calculations.
b Total volume (m^3) = duration (min) * flow rate (L/min)
c Air concentration (µg/m^3) = (mean residue (ng)/1000)/total volume m^3.
d Potential Inhalation Exposure (µg/hr) = air concentration (µg/m^3) x inhalation rate (m^3/hr) based on EPA SAC Policy No. 11 dated 2/22/01 (0.7 m^3/hr for children and 1.6 m^3/hr for adults).

Table 7. Summary of Residues of Metofluthrin on Dosimeter Samples

Body Area	Residue (µg)			Correct Residue[c] (µg)			Mean Residue (µg)	Correct Residue[d] (µg/cm^2)			Mean Residue (µg/cm^2)
	Run 1	Run 2	Run 3	Run 1	Run 2	Run 3		Run 1	Run 2	Run 3	
Lower Right Leg	0.268[a]	0.268[b]	0.268[b]	0.268	0.268	0.268	0.2675	0.01	0.01	0.01	0.0107
Upper Right Leg	0.268[b]	1.15	0.536	0.268	1.62	0.75	0.878	0.01	0.06	0.03	0.0351
Lower Torso	0.268[b]	0.841	1.43	0.268	1.18	2.01	1.15	0.01	0.05	0.08	0.046
Upper Torso	0.268[a]	0.268[a]	0.268[a]	0.268	0.268	0.268	0.2675	0.01	0.01	0.01	0.0107
Chest	0.268[a]	0.268[a]	0.268[a]	0.268	0.268	0.268	0.2675	0.01	0.01	0.01	0.0107
Lower Right Arm	0.268[a]	0.268[a]	0.268[a]	0.268	0.268	0.268	0.2675	0.01	0.01	0.01	0.0107
Upper Left Leg	0.268[a]	0.268[a]	0.268[a]	0.268	0.268	0.268	0.2675	0.01	0.01	0.01	0.0107

a Residues were not detected, therefore, ½ the LOQ was used for all calculations.
b Residues were < LOQ of 0.535 µg/sample, therefore, ½ the LOQ was used for all calculations.
c Residues were corrected based on a mean low field fortification recovery of 71.3%.
d Corrected residue (µg/cm^2) = Corrected residue (µg) / Patch size (25 cm^2)

Table 8. Summary of Residues of Metofluthrin in Wipes

Sample Type	Residue (µg)			Mean Residue (µg)	Correct Residue[b] (µg/cm^2)			Mean Residue (µg/cm^2)
	Run 1	Run 2	Run 3		Run 1	Run 2	Run 3	

DSS	0.54[a]	0.54[a]	0.54[a]	0.54	0.03	0.03	0.03	0.03
IPA	1.52	1.73	1.86	1.7	0.1	0.11	0.12	0.11

a Residues were < LOQ of 1.07µg/sample, therefore, ½ the LOQ was used for all calculations.
b Corrected Residue (µg/cm^2) = Residue (µg) / Wipe size (16 cm^2)

Name:
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APPENDIX A
Compliance Checklists for

"Measurement of Air Concentration and Deposition on Cotton Dosimeters of Metofluthrin Generated by a Personal Outdoor Insect Repellant Device in an Outdoor Environment"

GUIDELINE 875.2400 and GUIDELINE 875.2500

DRAFT

COMPLIANCE CHECKLIST
GUIDELINES 875.2400 and 875.2500
DERMAL AND INHALATION EXPOSURE MONITORING
POSTAPPLICATION

$ *The test substance must be the typical end use product of the active ingredient.* This criterion was met.

$ *The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case-by-case basis.* This criterion does not apply to this study. There was no mention of metabolites, breakdown products, or other contaminants.

$ *Applications should occur at the time of season that the end-use product is normally applied to achieve intended pest control.* This criterion was met. The site was an outdoor residential patio setting during fall evening hours in a warm climate when mosquito activity would be expected.

$ *Initiating testing immediately before a precipitation event should be avoided.* It is unclear if this criterion was met. Precipitation was not reported in the Study Report.

$ *The end use product should be applied by the application method recommended for the crop. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included.* This criterion does not apply to this study. The end-use product was a personal insect repellent worn on clothing.

$ *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases.* An application rate was not provided in the Study Report. According to MRID 464020-05 ("Metofluthrin: Non-Dietary (Residential) Risk Assessment and Personal Outdoor Insect Repellent Device" October 25, 2004; J. Driver and J. Ross), during a 12-hour period of use, the manufacturer S.C. Johnson & Son, Inc., has estimated the emission rate of metofluthrin from the Norm-1 device as ranging from 0.4 to 0.7 mg/hr.

$ *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion does not apply to this study.

$ *A sufficient number of replicates should be generated to address the exposure issues associated with each population of interest. In general, the study should include minimum of 15 replicates per activity, distributed as follows: 5 replicates (i.e., individuals) on each of 3 monitoring periods (i.e., "n" days after application).* This criterion was partially met. Three separate runs were conducted, during which time 21 replicates were obtained for dosimeter samples. The number of samples for this matrix was sufficient considering the experimental design; however, only three replicates were obtained for both the DSS and IPA wipe samples and a total of six adult samples and six child samples were obtained for the OVS tubes.

$ *The monitoring period should be of sufficient duration to result in reasonable detectability on dosimeters.*

Monitoring should be conducted before residues have dissipated beyond the limit of quantification. Baseline samples should be collected before the exposure activity commences. This criterion was not met. Baseline samples were not collected prior to the study and many of the samples for both the dosimeters, OVS tubes and wipes were below the level of quantification or detection.

$ *Activities monitored must be clearly defined and representative of typical practice.* This criterion was mostly met. The study was conducted in an outdoor residential setting and represented six hours of potential exposure that reflected a typical duration for outdoor residential activities. However, the manikins were stationary and therefore, were not engaged in any activities involving movement that may be more typical of residential outdoor activities.

$ *Inhalation exposure studies must be carried out concurrently with dermal exposure and transferable residue studies.* This criterion was met.

$ *Passive dosimetry studies must be carried out concurrently with transferrable residue studies.* This criterion was met.

$ *The selected sites and seasonal timing of monitoring must be appropriate to the activity.* This criterion was met.

$ *Studies should be conducted under different geographic/climatologic sites.* This criterion was not met. The study was only conducted in one location.

$ *Inhalation monitoring techniques area (i.e., stationary and/or personal monitoring) should contain sufficient samples to characterize the likely range of possible exposure concentrations, and to ensure that the reentry scenario can be adequately addressed.* This criterion was probably met. Six adult samples and six child samples were obtained for the OVS tubes.

$ *Particulate levels should be monitored along with vapor phase concentrations unless adequate justification for not doing so is provided.* This criterion does not apply to this study.

$ *Retention and breakthrough studies should be performed under conditions similar to those anticipated in the field phase of the study.* This criterion was not met. Retention and breakthrough studies were not conducted.

$ *The sampling technique used should be appropriate, given the expected exposure scenario (e.g., the use of personal sampling pumps and sampling times consisting of filter cassettes and resin tubes or polyurethane foam filters is preferred; where personal sampling is not appropriate, stationary monitoring may be conducted.)*

< *Personal sampling pumps should be clipped to the collar in the breathing zone of the test subject.* This criterion was mostly met. Air sampling tubes were clipped to the manikins in the breathing zone.

< *Stationary samples should be collected from the center of treated fields and from at least 4 other locations, preferably at the cardinal compost points from the center location.* This criterion was not met. Air samples were only collected from the manikins.

< *Indoor sampling strategies should be designed based on the nature of the exposure scenario and building type. Samples should be collected at heights representing the breathing zones of the exposed populations (e.g., 18 inches for children; 48 inches for adults).* This criterion was met.

$ *The duration of the sampling interval and air flow rates should be maximized within the appropriate flow rate range to increase the potential for capturing enough residue to be quantifiable.* These criteria were partially met. Samples were collected using an approximate air flow rate of 2 L/min and sampling durations of 3 hours. Residues were mostly non-quantifiable under these conditions.

$ *Air flow rates should be recorded at the initiation and termination of the monitoring period, with the average being used in all calculations.* This criterion was not met. Air flow rates were not provided in the Study Report.

$ *The sampling techniques (e.g., patches, whole-body dosimeters, hand rinse, gloves, fluorescent tracer) should be appropriate to the activities being monitored. The construction materials and location (i.e., inside or outside clothing) of monitoring devices and numbers (e.g., patches) should be appropriate to the use scenario. Hand rinse solutions must be appropriate to the pesticide being evaluated (i.e., selection of aqueous surfactants vs. isopropanol or other solutions, based on the physical chemical properties of the pesticide being evaluated.* This criterion was met.

$ *Sufficient control samples should be collected.* This criterion was met.

$ *Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analyses. Information of storage stability should be provided.* This criterion was probably met. A storage stability study was not mentioned in the Study Report.

$ *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery) and limit of quantification (LOQ) should be provided.* This criterion was partially met. Laboratory control fortification samples were analyzed to ensure the method was working properly; however, no information was provided on the determination of the LOQ.

$ *Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study.* This criterion was met.

$ *Raw residue data must be corrected if appropriate recovery values are less than 90 percent.* This criterion was not met.

$ *Dermal residues should be reported as mg or µg of pesticide active ingredient per body part sampled, if generated using the whole-body dosimetry techniques and on a surface area basis if the data were generated using the patch techniques (i.e., normalized on patch sample surface area; µg/cm^2 or mg/cm^2). Distributional data should be reported, to the extent possible.* This criterion was not met. Residues were reported on a µg/sample basis.

$ *Inhalation residues should be reported as µg pesticide active ingredient per sample and as an airborne concentration (µg/m^3). Distributional data should be reported, to the extent possible.* This criterion was met.

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