UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 12, 2009

MEMORANDUM:

SUBJECT: Review of "Assessment of Potential Inhalation and Dermal Exposure to Zinc Pyrithione During Outdoor Painting of Ship Hulls with Commercial Antifoulant Paint Containing Zinc Omadine"

TO: Heather Garvie, Chemical Review Manager
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DP Barcode: D311326

Pesticide Chemical/No.: Zinc pyrithione (ZPT)/ 088002

MRID No.: 467070-01

Attached is a review of the above mentioned study. The primary review (Attachment 1) was written by Versar, Inc. and the secondary review was written by the Antimicrobials Division. An ethics review (Attachment 2) was also written by the OPP Human Research Ethics Reviewer. This review concluded that "Although there are many significant gaps in the documentation of the ethical conduct of the study, there is no clear evidence that the research was intended to harm participants, or that it was fundamentally unethical in other ways."

Secondary Review of MRID 467070-01"Assessment of Potential Inhalation and Dermal Exposure to Zinc Pyrithione During Outdoor Painting of Ship Hulls with Commercial Antifoulant Paint Containing Zinc Omadine"

The objective of this study was to quantify dermal and inhalation exposures during the spray application of antifouling paint to the hulls of commercial cargo and passenger ships. The ships were painted with an EPA registered paint formulation (#2693-187) that contained 3.80% zinc pyrithione (ZPT) and has a coverage of 130 ft^2 per gallon. Exposure monitoring was conducted at shipyards in Boston, Massachusetts (Trials A and D) and Freeport, Grand Bahama (Trials B and C). The Boston shipyard contained an excavated drydock and the Freeport shipyard contained a floating drydock.

Study Conditions

A total of 49 experienced workers in three job categories (pot man, spray man and line tender) participated in this study. The workers were monitored for 1-2 consecutive work cycles each over one or two test days and each work cycle consisted of the application of one coat of paint. One to three crews were monitored during each work cycle and each crew consisted of one to two members of each job category. Painting was done with airless spray guns without wands, fed by high-pressure hoses from compressed air-powered portable air pumps operating at 3,500-4,500 psi. The work cycle durations ranged from 57 to 412 minutes and the surface area painted per person ranged from 5,000 to 13,800 ft^2. The amount of ai handled per work cycle ranged from 9.82 to 39.2 lbs, 5.97 to 24.4 lbs; and 5.10 to 39.2 lbs for the pot men, line tenders and spray men respectively. A summary of the conditions of each trial is given in Table 1.

Table 1 – Shipyard Study Conditions

Trial	Ship Type	Gloves	Overspray Enclosure	Notes
A	Cruise Ship, 680' long, 91' beam, 20' draft	Cotton work gloves with rubberized palms	Plastic sheeting with some gaps	Same yard as Trial D. Entire hull below waterline was painted (27,600 ft^2) with two coats. One coat was applied each day and each day was a work cycle. Some overhead spraying was required to paint the bottom of the hull.
B	Mega Yacht, 171' long, 32' beam, 10' draft	Gauntlet style Nitrile	Plastic tenting with small exhaust fan	Same yard as Trial C. Entire hull below waterline was painted (6400 ft^2) with three coats. One coat was applied on day one and two coats were applied on day two. Each coat was a work cycle
C	Cargo Ship, 90' long, 33' beam, 14' draft	Gauntlet style Nitrile	No sheeting or tenting used	Same Yard as Trial B. Hull area = 5000 ft^2. Two coats were applied: one in early afternoon and one in evening. Each coat was a work cycle. Spray men also did line tending.
D	Cruise Ship, 614' long, 92.5' beam, 20' draft	Gauntlet style Nitrile	Plastic sheeting with more gaps than Trial A.	Same yard as Trail A. Narrow band at waterline painted (6800 ft^2) with two coats over two days. Each coat was a work cycle. No overhead spraying was required.

Sampling and Analytical Methods

To measure dermal exposure, workers wore 100% polyester whole-body dosimeters under clean work clothes, covered by a Tyvek® hooded coverall. Workers also wore a pair of 100% polyester dosimeter gloves under either work gloves with rubberized palms (Trial A) or Ansell #92-600 gauntlet-style nitrile gloves (Trials B, C and D). Two 100 cm^2 100% polyester pads were used to monitor head and neck exposure. One pad was placed on the back of the work shirt and the other was placed on the front of the coverall. Inhalation exposure was monitored using 37-mm glass fiber filters in closed face cassettes positioned in the breathing zone. The flow rate of the sampling pump was calibrated to 1.5 liters per minute.

The samples were collected, handled and analyzed in accordance with validated methods as described in the study report. Field and laboratory fortification samples were generated at two levels (2X LOQ and 150X LOQ) for each matrix. The results of the field fortification samples indicated that the recoveries were generally above 90% and that the fortification levels matched the dosimeter residue levels. The head/neck patch residues; however, were orders of magnitude above the highest field fortification levels.

Exposure Calculation Methods

The dermal exposures were calculated by adding the measured residues (i.e. ug/sample) of the whole body dosimeters and glove dosimeters to the estimated residues derived from the head and neck pads. The estimated residues were derived from the head and neck pad results (in ug/cm^2) by multiplying by the surface area represented by each pad. The surface area of the front of the head and neck was assumed to be 605 cm^2 based upon the area of the face not covered by a respirator (70% of 650 cm^2) and the area of the front of the neck (150 cm^2). The surface area of the rear of the head and neck was assumed to be 760 cm^2 which includes 650 cm^2 for the rear of the head and 110 cm^2 for the back of the neck. The dermal exposures are expressed as a unit exposures by dividing the amount of exposure by the amount of ai handled. During Trials A and D, one sample (i.e. monitoring unit) was collected per worker per day and during Trials B and C one or two samples per worker per day were collected. If two samples were collected per worker per day, the dermal exposures were calculated by averaging the two samples.

The inhalation exposures are expressed as time weighted average (TWA) air concentrations and include all of the samples collected on a worker for a workday. The TWA was calculated using the following formula:

$$TWA = \frac{(\text{Sample Time\#1} * \text{Air Concentration\#1}) + (\text{Sample Time\#2} * \text{Air Concentration\#2})}{(\text{Sample Time\#1} + \text{Sample Time\#2})}$$

To provide a basis for comparison to the ZPT inhalation toxicology endpoint, that is expressed as an human equivalent concentration (HEC), eight hour TWAs were also calculated. The 8 hour TWA was calculated for samples of greater than six hours duration by assuming zero exposure for the un-sampled portion of the workday to account for setup and cleanup time. The 8 hour TWA was calculated for samples of less than six hours of duration by assuming six hours of exposure to the measured concentration and two hours of zero exposure.

Results and Discussion

A summary of the results are included in Tables 1 and 2 and detailed listings are included in Appendix A. The maximum exposures occurred at Trial B because the work area was enclosed with plastic sheeting to contain overspray. The exposures were much lower for Trial C, which was conducted at the same shipyard as Trial B, because the work area was not as enclosed. The dermal exposure differences between Trials A and D were caused either by better gloves being worn during Trial D and/or by the fact that the entire hull below the water line was painted during Trial A, which required spraying upward to the bottom of the hull, while during Trial D only a band along side of the hull at the waterline was painted. These differences were most pronounced for the linetenders and potmen where the exposures were an order of magnitude lower for Trial D.

In many cases, the head and neck accounted for a significant portion of the dermal exposure. This is most pronounced for Trial B where the head and neck accounted for 90 to 98 percent of the dermal exposure. The head and neck was also a major contributor to the dermal exposures measured during Trial D when nitrile gloves were substituted for rubberized cotton gloves.

Table 1 – ZPT Shipyard Study Dermal Unit Exposures (mg/lb ai)

Trial	Job*	n	Whole Body Dosimeter		Gloves		Head/Neck		Total Dermal	
			Range	AVG	Range	AVG	Range	AVG	Range	AVG
A	SM	6	0.12 –1.0	0.36	0.36 - 2.3	1.2	0.07 - 2.2	0.55	0.62 - 5.2	2.2
	LT	5	0.11 - 0.39	0.28	0.41 - 4.3	1.6	0.05 - 1.4	0.67	1.3 - 4.5	2.5
	PM	5	0.02 - 0.13	0.07	0.18 - 1.7	0.67	0.04 - 0.13	0.07	0.38 - 1.8	0.8
B	SM	4[A]	0.6 - 3.3	1.5	0.05 - 0.21	0.12	3.4 – 10.8	6.1	4.4 - 12.3	7.8
	LT	4[A]	0.2 - 0.6	0.45	0.02 - 0.12	0.05	0.06 -10.2	2.7	0.4 -10.7	3.1
	PM	2[B]	0.13, 0.14	0.13	0.0004, 0.002	0.001	0.02, 0.03	0.02	0.14, 0.17	0.16
C	SM	1[C]	0.21	NA	0.023	NA	2.69	NA	2.92	NA
	LT	1[C]	0.19	NA	0.014	NA	0.22	NA	0.42	NA
	PM	1[C]	0.15	NA	0.006	NA	0.10	NA	0.25	NA
D	SM	4	0.04 - 0.16	0.09	0.08-0.31	0.19	0.3 - 3.3	1.5	0.6 - 3.4	1.8
	LT	3	0.01 - 0.26	0.10	0.005 - 0.019	0.014	0.02 - 0.28	0.11	0.07 - 0.30	0.22
	PM	5	0.003 - 0.01	0.006	0.001 - 0.004	0.003	0.013 - 0.52	0.030	0.02 - 0.06	0.039

A. Six samples were collected for the two SM and LT workers during Trial B. One sample per worker was collected on 1/4/2005 and two samples per worker were collected on 1/5/2005. The two samples taken on 1/5/2005 were averaged.

B. Three samples were collected for the one PM worker during Trial B. One sample was collected on 1/4/2005 and two samples were collected on 1/5/2005. The two samples taken on 1/5/2005 were averaged.

C. Two samples were collected for each worker during Trial C. Both were collected on 2/9/2005 and were averaged.

***Job:** **SM** = Spray Man, **LT** = Line Tender, **PM** = Pot Man

Table 2 – ZPT Shipyard Study Inhalation Exposures (ug/m^3)								
Trial	Job*	Sample Duration[A] (Minutes)			ZPT TWA[B] (ug/m^3)		ZPT 8 Hr TWA[C] (ug/m^3)	
		n	Range	Avg	Range	Avg	Range	Avg
A	SM	6	254-375	299	22.2–120	75.7	16.5-90	56.8
	LT	5	262-412	343	24.3–434	134	18.2-353	109
	PM	5	267-365	325	13.9–23.1	18.5	10.4- 17.3	13.9
B	SM	4	101-130	116	3812-6333	5274	2859-5228	3955
	LT	4	101-130	116	141-2074	756	106-1555	480
	PM	2	101,130	116	105,118	112	79, 89	84
C	SM	1	138	NA	396	NA	297	NA
	LT	1	138	NA	56.7	NA	42	NA
	PM	1	138	NA	50.4	NA	38	NA
D	SM	4	157-203	182	21.7-95.5	68.5	16-72	51
	LT	3	92-211	164	1.1-10.1	4.7	0.8-7.6	3.6
	PM	5	151-214	187	0.7-1.7	1.1	0.5-1.3	0.9

A. The sample duration includes the total time of all of the samples collected on a worker for a workday. One sample per worker per day was collected at sites A and D and one or two samples were collected per worker per day at sites B and C.

B. The time weighted average (TWA) air concentrations includes all of the samples collected on a worker for a workday

C. The 8 hour TWA was calculated for samples of greater than six hours duration by assuming zero exposure for the un-sampled portion of the workday to account for setup and cleanup time. The 8 hour TWA was calculated for samples of less than six hours of duration by assuming six hours of exposure to the measured concentration and two hours of zero exposure.

*Job: SM = Spray Man, LT = Line Tender, PM = Pot Man

Statistical Considerations

A statistical analysis will be performed to review the accuracy goals for occupational handler studies that have been discussed with the EPA Scientific Advisory Panel (SAP) and the EPA Human Studies Review Board (HSRB) and to determine which statistics should be used in assessing exposures. This analysis will be written as a separate report.

Limitations and Uncertainties

This study has the following limitations and uncertainties:

- It is not known if this study is representative of all shipyards where ZPT antifoulant paints might be applied.
- It is not known if the high results for the head and neck area are due to actual exposures or if they are an artifact of the patch method of monitoring.
- It is not clear which workers correspond to which monitoring units because a list that links workers to monitoring units was not provided in the study report.
- The entire workday was not sampled which leads to uncertainty in the inhalation exposure 8 hour TWAs. This situation is most significant for sites B and C where the total sample duration ranged from 101 to 138 minutes per worker per day.

Conclusions

This study meets most of the applicable series 875 guidelines and is acceptable for use in risk assessment provided that the above mentioned limitations and uncertainties are considered.

Secondary Review of MRID 467070-01 - Appendix A

Spreadsheet 1 - Inhalation Results Sorted By Trial

Replicate	Trial	Date	Cycle	Sample Duration (minutes)	TWA Duration (minutes)	Job	ZPT Lb ai Handed	ZPT in Air (ug/m3)	ZPT TWA (ug/m3)	ZPT 8 Hr TWA
1	A	11/6/2004	1	375	375	Spray Man	39.2	34.5	34.5	27
6	A	11/6/2004	1	360	360	Spray Man	38	97.2	97.2	73
9	A	11/7/2004	2	271	271	Spray Man	20.3	86.9	86.9	65
10	A	11/7/2004	2	271	271	Spray Man	12.7	22.2	22.2	17
13	A	11/7/2004	2	262	262	Spray Man	29.2	93.4	93.4	70
15	A	11/7/2004	2	254	254	Spray Man	7.5	120	120	90
Minimum				254	254		7.5	22.2	22.2	16.7
GM				309	309		17.1	64.3	64.3	49.3
AM				299	299		24.5	75.7	75.7	57.0
Maximum				375	375		39.2	120.0	120.0	90.0
2	A	11/6/2004	1	412	412	Line Tender	9.5	114	114	98
3	A	11/6/2004	1	390	390	Line Tender	24.4	434	434	353
4	A	11/6/2004	1	385	385	Line Tender	9.5	46	46	37
12	A	11/7/2004	2	262	262	Line Tender	20.3	53.6	53.6	40
16	A	11/7/2004	2	265	265	Line Tender	20.3	24.3	24.3	18
Minimum				262	262		9.5	24.3	24.3	18.2
GM				330	330		20.3	52.6	52.6	42.2
AM				343	343		16.8	134.4	131.0	109.2
Maximum				412	412		24.4	434.0	434.0	352.8
5	A	11/6/2004	1	360	360	Pot Man	38	18.3	18.3	14
7	A	11/6/2004	1	350	350	Pot Man	39.2	13.9	13.9	10
8	A	11/6/2004	1	365	365	Pot Man	39.2	18.4	18.4	14
11	A	11/7/2004	2	281	281	Pot Man	40.6	23.1	23.1	17
14	A	11/7/2004	2	267	267	Pot Man	29.2	18.6	18.6	14
Minimum				267	267		29.2	13.9	13.9	10.4
GM				310	310		33.3	18.4	18.4	13.8
AM				325	325		37.2	18.5	18.5	13.9
Maximum				365	365		40.6	23.1	23.1	17.3
18	B	1/4/2005	1	101	101	Spray Man	6.97	5190	5190	3893
19	B	1/4/2005	1	101	101	Spray Man	10.9	5760	5760	4320
22	B	1/5/2005	2	67		Spray Man	9.83	6420		
27	B	1/5/2005	3	63		Spray Man	6.85	6240		
(22/27)					**130**				**6333**	**4750**
26	B	1/5/2005	2	67		Spray Man	7.38	6970		
31	B	1/5/2005	3	63		Spray Man	5.1	454		
(26/31)					**130**				**3812**	**2859**
Minimum				63	101		5	454	3812	2859
GM				75	115		8	3949	5183	3887
AM				77	116		9	5172	5274	3956
Maximum				101	130		11	6970	6333	4750
17	B	1/4/2005	1	101	101	Line Tender	8.95	240	240	180
20	B	1/4/2005	1	101	101	Line Tender	8.95	571	571	428
24	B	1/5/2005	2	67		Line Tender	8.6	176		132
28	B	1/5/2005	3	63		Line Tender	5.97	104		
(24,28)					**130**				**141**	**106**
25	B	1/5/2005	2	67		Line Tender	8.6	3350		
29	B	1/5/2005	3	63		Line Tender	5.97	716		
(25,29)					**130**				**2074**	**1555**
Minimum				63	101		6.0	104	141	105.8
GM				80	115		7.3	415	447	529.1
AM				77	116		7.8	660	755	830.7
Maximum				101	130		9.0	3350	2074	1555.1

Secondary Review of MRID 467070-01 - Appendix A

Spreadsheet 1 - Inhalation Results Sorted By Trial

Replicate	Trial	Date	Cycle	Sample Duration (minutes)	TWA Duration (minutes)	Job	ZPT Lb al Handed	ZPT in Air (ug/m3)	ZPT TWA (ug/m3)	ZPT 8 Hr TWA
21	B	1/4/2005	1	101	101	Pot Man	17.9	105	105	79
23	B	1/5/2005	2	67		Pot Man	17.2	141		
30	B	1/5/2005	3	63		Pot Man	11.9	94.4		
(23,30)					**130**				**118**	**89**
Minimum				63	101		11.9	94.4	105	79
GM				80	101		14.6	98.6	112	84
AM				77	101		15.7	113.5	112	84
Maximum				101	101		17.9	141.0	118	89
34	C	2/9/2005	1	57		Spray Man	9.8	402		
35	C	2/9/2005	2	81		Spray Man	10.6	391		
(34,35)					**138**				**396**	**297**
33	C	2/9/2005	1	57		Line Tender	9.82	53.6		
37	C	2/9/2005	2	81		Line Tender	10.6	58.8		
(33,37)					**138**				**57**	**42**
32	C	2/9/2005	1	57		Pot Man	9.82	42.2		
36	C	2/9/2005	2	81		Pot Man	10.6	56.2		
(32,36)					**138**				**50**	**38**
39	D	4/16/2005	1	203	203	Spray Man	9.8	84.1	84.1	63
40	D	4/16/2005	1	184	184	Spray Man	5.7	21.7	21.7	16
48	D	4/17/2005	2	182	182	Spray Man	10.2	95.5	95.5	72
49	D	4/17/2005	2	157	157	Spray Man	8.3	72.5	72.5	54
Minimum				157	157		5.7	21.7	21.7	16.3
GM				181	181		8.3	59.6	59.6	44.7
AM				182	182		8.5	68.5	68.5	51.3
Maximum				203	203		10.2	95.5	95.5	71.6
38	D	4/16/2005	1	211	211	Line Tender	9.8	1.1	1.1	0.83
44	D	4/17/2005	2	190	190	Line Tender	10.2	10.1	10.1	7.58
50	D	4/17/2005	2	92	92	Line Tender	8.3	3	3	2.25
Minimum				92	92		8.3	1.10	1.10	0.83
GM				155	155		9.4	3.22	3.22	2.41
AM				154	154		9.4	4.37	4.73	3.55
Maximum				211	211		10.2	10.10	10.10	7.58
42	D	4/16/2005	1	151	151	Pot Man	15.5	1.1	1.1	0.8
43	D	4/16/2005	1	163	163	Pot Man	15.5	0.7	0.7	0.5
45	D	4/17/2005	2	210	210	Pot Man	18.5	0.8	0.8	0.6
46	D	4/17/2005	2	214	214	Pot Man	18.5	1.4	1.4	1.1
47	D	4/17/2005	2	199	199	Pot Man	18.5	1.7	1.7	1.3
Minimum				151	151		15.5	0.70	0.70	0.53
GM				186	186		17.2	1.08	1.08	0.81
AM				187	187		17.3	1.14	1.14	0.86
Maximum				214	214		18.5	1.70	1.70	1.28

Note - Numbers in bold indicate that samples taken from the same worker on the same workday were combined.

Secondary Review of MRID 467070-01 - Appendix A

Spreadsheet 2 - Dermal Results and Unit Exposures Sorted By Trial

Replicate	Trial	Date	Cycle	Sample Duration (minutes)	Job	ZPT Lb ai Handed	WBD (mg/sample)	WBD Unit Exposure (mg/lb ai)	Head/Neck Pads (mg/sample)	Head/Neck Unit Exposure (mg/lb ai)	Dosimeter Gloves (mg/sample)	Hand Unit Exposure (mg/lb ai)	ZPT Dermal Exposure (mg/sample)	Dermal Unit Exposure (mg/lb ai)
1	A	11/6/2004	1	375	Spray Man	39.2	4.75	0.12	2.57	0.07	66.5	1.70	73.8	1.88
6	A	11/6/2004	1	360	Spray Man	38.0	6.83	0.18	2.98	0.08	13.6	0.36	23.4	0.62
9	A	11/7/2004	2	271	Spray Man	20.3	5.76	0.28	11.8	0.58	8.87	0.44	26.4	1.30
10	A	11/7/2004	2	271	Spray Man	12.7	3.73	0.29	4.36	0.34	29.7	2.34	37.8	2.98
13	A	11/7/2004	2	262	Spray Man	29.2	7.84	0.27	1.39	0.05	19	0.65	28.2	0.97
15	A	11/7/2004	2	254	Spray Man	7.5	7.72	1.03	16.5	2.20	14.5	1.93	38.72	5.16
Minimum				254		7.5	3.7	0.12	1.4	0.0	8.9	0.36	23.4	0.62
GM				309		17.1	6.1	0.35	6.5	0.4	31.1	1.8	53.5	3.1
AM				299		24.5	6.1	0.36	6.6	0.6	25.4	1.2	38.1	2.2
Maximum				375		39.2	7.8	1.03	16.5	2.2	66.5	2.3	73.8	5.2
2	A	11/6/2004	1	412	Line Tender	9.5	3.71	0.39	13.6	1.43	11.1	1.17	26.4	2.99
3	A	11/6/2004	1	390	Line Tender	24.4	6.2	0.25	14.5	0.59	10.1	0.41	30.8	1.26
4	A	11/6/2004	1	385	Line Tender	9.5	3.6	0.38	7.28	0.77	4.88	0.51	15.8	1.66
12	A	11/7/2004	2	262	Line Tender	20.3	5.73	0.28	10.5	0.52	29.8	1.47	46.0	2.27
16	A	11/7/2004	2	265	Line Tender	20.3	2.27	0.11	0.922	0.05	88	4.33	91.2	4.49
Minimum				262		9.5		0.11		0.05		0.41		1.3
GM				330		20.3		0.21		0.25		2.25		3.7
AM				343		16.8		0.28		0.67		1.58		2.5
Maximum				412		24.4		0.39		1.43		4.33		4.5
5	A	11/6/2004	1	360	Pot Man	38.0	1.2	0.032	1.91	0.05	15.4	0.41	18.5	0.49
7	A	11/6/2004	1	350	Pot Man	39.2	0.969	0.025	1.6	0.04	67	1.71	89.6	1.77
8	A	11/6/2004	1	365	Pot Man	39.2	3.08	0.079	5.08	0.13	20.8	0.53	29.0	0.74
11	A	11/7/2004	2	281	Pot Man	40.6	5.34	0.132	3.05	0.08	7.23	0.18	15.6	0.38
14	A	11/7/2004	2	267	Pot Man	29.2	2.95	0.101	1.32	0.05	16	0.55	20.3	0.69
Minimum				267		29.2		0.025		0.04		0.18		0.4
GM				310		33.3		0.056		0.05		0.47		0.6
AM				325		37.2		0.073		0.07		0.67		0.8
Maximum				365		40.6		0.132		0.13		1.71		1.8
18	B	1/4/2005	1	101	Spray Man	7.0	8.86	1.27	75.4	10.82	1.44	0.207	85.7	12.30
19	B	1/4/2005	1	101	Spray Man	10.9	35.9	3.29	55.8	5.12	0.569	0.052	92.3	8.47
22	B	1/5/2005	2	67	Spray Man	9.8	5.05	0.51	43.7	4.45	0.525	0.053	49.3	5.01
27	B	1/5/2005	3	63	Spray Man	6.9	4.27	0.62	42.1	6.15	0.511	0.075	46.9	6.84
(22/27)				**130**				**0.57**		**5.30**		**0.064**		**5.93**
26	B	1/5/2005	2	67	Spray Man	7.4	6.35	0.86	42.4	5.75	1.44	0.195	50.2	6.80
31	B	1/5/2005	3	63	Spray Man	5.1	4.92	0.96	4.82	0.95	0.617	0.121	10.4	2.03
(26/31)				**130**				**0.91**		**3.35**		**0.158**		**4.42**
Minimum				101				0.57		3.35		0.052		4.42
GM				115				1.21		5.60		0.102		7.22
AM				116				1.51		5.14		0.120		7.78
Maximum				130				3.29		10.82		0.207		12.30
17	B	1/4/2005	1	101	Line Tender	9.0	2.11	0.24	1.11	0.12	0.252	0.03	3.5	0.39
20	B	1/4/2005	1	101	Line Tender	9.0	5.19	0.58	2.06	0.23	1.07	0.12	8.3	0.93
24	B	1/5/2005	2	67	Line Tender	8.6	2.93	0.34	0.662	0.08	0.183	0.02	3.8	0.44
28	B	1/5/2005	3	63	Line Tender	6.0	3.19	0.53	0.252	0.04	0.074	0.01	3.5	0.58
(24/28)				**130**				**0.44**		**0.06**		**0.02**		**0.51**
25	B	1/5/2005	2	67	Line Tender	8.6	3.16	0.37	165	19.19	0.172	0.02	168.3	19.57
29	B	1/5/2005	3	63	Line Tender	6.0	4.3	0.72	6.94	1.16	0.112	0.02	11.4	1.90
(25/29)				**130**				**0.54**		**10.17**		**0.02**		**10.74**

Secondary Review of MRID 467070-01 - Appendix A

Spreadsheet 2 - Dermal Results and Unit Exposures Sorted By Trial

Replicate	Trial	Date	Cycle	Sample Duration (minutes)	Job	ZPT Lb ai Handed	WBD (mg/sample)	WBD Unit Exposure (mg/lb ai)	Head/Neck Pads (mg/sample)	Head/Neck Unit Exposure (mg/lb ai)	Dosimeter Gloves (mg/sample)	Hand Unit Exposure (mg/lb ai)	ZPT Dermal Exposure (mg/sample)	Dermal Unit Exposure (mg/lb ai)
Minimum				101				0.24		0.06		0.02		0.39
GM				115				0.42		0.36		0.03		1.18
AM				116				0.45		2.65		0.05		3.14
Maximum				130				0.58		10.17		0.12		10.74
21	B	1/4/2005	1	101	Pot Man	17.9	2.46	0.14	0.481	0.03	0.042	0.002	3.0	0.17
23	B	1/5/2005	2	67	Pot Man	17.2	1.7	0.10	0.27	0.02	0.002	0.0001	2.0	0.11
30	B	1/5/2005	3	63	Pot Man	11.9	1.85	0.16	0.226	0.02	0.008	0.0007	2.1	0.18
(23,30)				**130**				**0.13**		**0.02**		**0.0004**		**0.14**
AM						15.7		0.13		0.02		0.001		0.16
34	C	2/9/2005	1	57	Spray Man	9.8	1.6	0.16	41.3	4.21	0.4	0.038	43.3	4.41
35	C	2/9/2005	2	81	Spray Man	10.6	2.7	0.25	12.4	1.17	0.1	0.008	15.1	1.43
(34,35)				**138**				**0.21**		**2.68**		**0.023**		**2.92**
33	C	2/9/2005	1	57	Line Tender	9.8	2.74	0.28	2.31	0.24	0.017	0.002	5.1	0.52
37	C	2/9/2005	2	81	Line Tender	10.6	1.05	0.10	2.19	0.21	0.277	0.026	3.5	0.33
(33,37)				**138**				**0.19**		**0.22**		**0.014**		**0.42**
32	C	2/9/2005	1	57	Pot Man	9.8	1.53	0.16	1.09	0.11	0.115	0.012	2.7	0.28
36	C	2/9/2005	2	81	Pot Man	10.6	1.54	0.15	0.845	0.08	0.006	0.001	2.4	0.23
(32,36)				**138**				**0.15**		**0.10**		**0.006**		**0.25**
39	D	4/16/2005	1	203	Spray Man	9.8	0.438	0.045	2.52	0.26	3.02	0.31	5.98	0.61
40	D	4/16/2005	1	184	Spray Man	5.7	0.476	0.084	18.5	3.26	0.438	0.08	19.41	3.42
48	D	4/17/2005	2	182	Spray Man	10.2	1.6	0.157	3.61	0.35	1.67	0.16	6.88	0.67
49	D	4/17/2005	2	157	Spray Man	8.3	0.775	0.093	18.3	2.20	1.61	0.19	20.69	2.49
Minimum				157		5.7		0.045		0.3		0.08		0.61
GM				181		8.3		0.086		0.9		0.17		1.37
AM				182		8.5		0.095		1.5		0.19		1.80
Maximum				203		10.2		0.157		3.3		0.31		3.42
38	D	4/16/2005	1	211	Line Tender	9.8	0.233	0.024	0.247	0.03	0.174	0.0177	0.65	0.067
44	D	4/17/2005	2	190	Line Tender	10.2	0.06	0.006	2.85	0.28	0.056	0.0055	2.97	0.291
50	D	4/17/2005	2	92	Line Tender	8.3	2.15	0.258	0.174	0.02	0.157	0.0189	2.48	0.298
Minimum				92		8.3		0.006		0.02		0.0055		0.067
GM				155		9.4		0.033		0.05		0.0122		0.179
AM				164		9.4		0.096		0.11		0.0140		0.219
Maximum				211		10.2		0.258		0.28		0.0189		0.298
42	D	4/16/2005	1	151	Pot Man	15.5	0.039	0.0025	0.197	0.013	0.018	0.0010	0.25	0.016
43	D	4/16/2005	1	163	Pot Man	15.5	0.196	0.0126	0.562	0.036	0.043	0.0028	0.80	0.052
45	D	4/17/2005	2	210	Pot Man	18.5	0.113	0.0061	0.627	0.034	0.078	0.0041	0.82	0.044
46	D	4/17/2005	2	214	Pot Man	18.5	0.066	0.0036	0.289	0.016	0.049	0.0026	0.40	0.022
47	D	4/17/2005	2	199	Pot Man	18.5	0.088	0.0048	0.962	0.052	0.039	0.0021	1.09	0.059
Minimum				151		15.5		0.0025		0.013		0.0010		0.016
GM				186		17.2		0.0051		0.026		0.0023		0.034
AM				187		17.3		0.0056		0.030		0.0025		0.039
Maximum				214		18.5		0.0126		0.052		0.0041		0.059

Note - Numbers in bold indicate that samples taken from the same worker on the same workday were combined.

Secondary Review of MRID 467070-01 - Appendix A

Spreadsheet 3 - Site Conditions

Site	Dry Dock Type	Labor Source	Trial	Ship Type	Date	Clothing	Gloves	Site Characteristics	Worker Rotation	Notes
Boston	Excavated	Contractor	A	Cruise Ship, 680' Long, 91' Beam, 20' Draft	Nov-04	LS Flannel shirt and jeans	Cotton Gloves with Rubberized Palms	Plastic Sheeting with Some Gaps	Always	Entire Hull below waterline was painted (27,600 ft2) with two coats. One coat was applied each day. Each day was a work cycle
Freeport	Floating	Yard	B	Mega Yacht, 171' long, 32' beam, 10' draft	Jan-05	SS cotton work shirt and cotton twill work pants	Ansell #92-600 Nitrile	Plastic Tenting with Exhaust Fan	None	Entire hull below waterline was painted (6400 ft2) with three coats. One coat was on day one. Two were applied on day two. Each coat was a work cycle
Freeport	Floating	Yard	C	Dry Cargo Ship, 90' long, 33' beam, 14' draft	Feb-05	SS cotton work shirt and cotton twill work pants	Ansell #92-600 Nitrile	No sheeting or tenting used	None	Same Yard as Trial C. Hull area = 5000 ft2. Two coats were applied one in early afternoon and one in evening. Each coat was a work cycle. Spray men also did line tending.
Boston	Excavated	Contractor	D	Cruise Ship, 614' long, 92.5' beam, 20' draft	Apr-05	Cotton Tshirt and Jeans	Ansell #92-600 Nitrile	Plastic Sheeting with more gaps than trial A.	Some	Narrow band at waterline painted (6800 ft2) with two coats over two days. Each coat was a work cycle.

Reviewer: Traci Brody/Ron Lee **Date** June 28, 2006

STUDY TYPE: Antifoulant Application Worker Exposure Monitoring Study

TEST MATERIAL: Intersmooth 460 SPC Antifouling Paint - BEA468 (brown) and 469 (red)
Interlux Micron 66 – YBA473 (black)
Intersmooth 460 SPC Antifouling Paint – BEA462 (blue)
Each test substance (paint) was formulated with 3.80% zinc pyrithione (ZPT) by weight.

SYNONYMS: 2-mercaptopyridine-1-oxide zinc salt; 2-mercaptopyridine n-oxide zinc salt; Zinc pyrithione; ZNPT; 2-pyridinethiol-1-oxide, zinc salt; bis-(1-hydroxy-2(1H)-pyridinethionato-O,S)zinc; bis(1-hydroxy-2(1H)-pyridinethionato)zinc; bis(2-pyridylthio)zinc 1,1'-dioxide; bis(2-pyridylthio)zinc, N,N'-dioxide; De-Squaman; OM-1563; omadine zinc; Pyridinethiol-1-oxide, zinc salt; Pyrithione zinc; vancide p; Vancide ZP; zinc 1-hydroxy-2-pyridine-thione; Zinc 1-hydroxypyridine-2-thione; Zinc 2-mercaptopyridine-N-oxide; Zinc 2-pyridinethiol-1-oxide; Zinc, bis(1-hydroxy-2(1H)-pyridinethionato-O,S)-, (T-4)-; Zinc, bis(2-pyridylthio)-, N,N,'-dioxide; Zinc omadine; Zinc polyanemine; Zinc PT; Zinc pyridine-2-thiol-1-oxide; Zinc pyridinethione; Zinc-pyrion; CAS # 13463-41-7.

CITATION:

Director/Author:	Mark G. Bookbinder, Ph.D.
Title:	*Assessment of Potential Inhalation and Dermal Exposure to Zinc Pyrithione During Outdoor Painting of Ship Hulls With Commercial Antifouling Paint Containing ZINC OMADINE®*
Report Date:	November 22, 2005
Performing Laboratories:	BOOKBINDER (Primary Testing Facility) 11157 Yellow Leaf Way Germantown, MD 20876-1377 Arch Chemicals (Primary Analytical Laboratory) 350 Knotter Drive Cheshire, CT 06410 Pharmalytica Services (Assisting Analytical Laboratory) 683 N. Mountain Road Newington, CT 06111
Identifying Codes:	Study Identification Number: BWE03001 MRID 467070-01

SPONSOR: ManLi Wu, Ph.D. (Sponsor's Representative)
Arch Chemicals
350 Knotter Drive
Cheshire, CT 06410

Attachment (1)

EXECUTIVE SUMMARY:

The objective of this study was to quantify the dermal and inhalation exposure encountered by dry dock workers performing the essential tasks for the commercial application of antifouling paint to portions of the hulls of commercial cargo and passenger ships. Exposure monitoring was conducted at shipyards in Boston, Massachusetts (Trials A and D) and Freeport, Grand Bahama (Trials B and C). These facilities were selected to represent a range of geographic locations, formulations used, vessel types treated, and application parameters. The ships were painted with either Intersmooth® 460 SPC antifouling paint or Interlux Micron® 66 antifouling paint, formulated with Zinc Omadine Power AF, both of which contain 3.80% zinc 2-pyridinethiol 1-oxide). The mean amounts of Monitoring was conducted in November 2004 (Trial A), January 2005 (Trial B), February 2005 (Trial C), and April 2005 (Trial D).

A total of 49 experienced dry dock workers participated in the study. The test subjects represented three dry dock job categories: pot man, spray man, and line tender. The workers were monitored for 1-2 consecutive work cycles each over one or two test days. Treatment was conducted by airless spray guns without wands, fed by high-pressure hoses from compressed air-powered portable air pumps operating at 3,500-4,500 psi. The work cycle durations ranged from 57 minutes to 6 hours 52 minutes and the surface area treated per person ranged from 5,000 to 27,604 ft^2. The pot men handled 9.82 to 39.22 lbs ai; line tenders were exposed to 5.97 to 24.36 lbs ai; and spray men applied 5.10 to 39.22 lbs ai.

To measure dermal exposure, workers wore 100% polyester whole-body dosimeters under clean work clothes, covered by a Tyvek® hooded coverall. Workers also wore a pair of 100% polyester dosimeter gloves under either work gloves (Trial A) or Ansell #92-600 gauntlet-style nitrile chemical resistant gloves (Trials B-D). Two 100 cm^2 100% polyester pads were used to monitor head and neck exposure. One pad was placed on the back of the work shirt, the other exposed on the front of his coverall. Inhalation exposure was monitored using an air sampling train consisting of a 37-mm binder-free glass fiber filter in an opaque, conductive polypropylene cassette attached to the front of the worker's coverall in the worker's breathing zone. The outlet tube was connected to a second cassette containing a mixed cellulose ester filter, then by Tygon and vinyl tubing to a Buck Model S.S.™ air sampling pump worn on his belt. The pump was calibrated to deliver an air flow rate of approximately 1.5 liters per min. (LPM).

Versar estimated dermal and inhalation exposure values as μg/lb ai handled. Average field fortification recoveries, calculated by fortification level and matrix from each trial separately, were used to adjust the field residues if the recoveries were less than 90%. To calculate the inhalation exposures, Versar adjusted the flow rate of each worker by an average breathing rate of 0.0167 m^3/min. for light activities. The Registrant provided dermal and inhalation exposure values expressed as μg/lbs ai handled and μg/kg body weight/lbs ai handled. The Registrant corrected the raw field data based on average field fortification recoveries of the appropriate matrix exposed in the field on the same day. Adjustments were not made when recoveries from the field control samples were >100%. Inhalation exposures were normalized for the pump flow rate of 1.5 L/min. to a breathing rate of 1,500 L/hr for moderate activities, then by adjustment for standard worker body weight (70 kg).

Versar used the Shapiro-Wilks test on both non-transformed and log-transformed data to test for normality and lognormality, respectively (tested for $p \geq 0.05$ and $p \geq 0.01$). These tests were conducted for total potential dermal exposure (expressed in terms of ug/lb ai). When the data were grouped by job function across all trials, significant non-normality was found for all jobs, and no significant non-lognormality was found at the $p \geq 0.05$ significance level. When the data were grouped for each trial across all job functions, significant non-normality was found for all trials, and no significant non-lognormality was found at the $p \geq 0.05$ significance level. These results suggest that the data for a given job function or for a given trial are lognormally distributed. Therefore, the appropriate measure of central tendency for data grouped by job function or by trial is the geometric mean. **[EPA Note: The appropriate measure of central tendency will be determined based on a separate statistical analysis.]**

Exposure values were summarized two ways: by trial and by job function. When summarizing exposures over a single trial, it was assumed that the job functions performed by the replicates were representative of the type of work typically performed in painting operations, and that the work was divided in a representative fashion. Therefore, the geometric mean was taken over all workers. When summarizing exposures for a given job function over all trials, it was assumed that each trial had equal weight, regardless of the number of replicates monitored for each trial.

Therefore, for a given job function, four geometric means were calculated (one for each trial) and the arithmetic mean of the four geometric means was calculated as a summary statistic.

Dermal exposure was estimated by measuring residues on or in inner whole body dosimeters, head/neck pads, and dosimeter gloves. The overall geometric means for total dermal exposure were 1,410, 1,530, 639, and 177 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 284, 2,904, and 1,030 μg/lb ai for pot men, spray men, and line tenders, respectively.

Versar calculated hand exposures based on dosimeter gloves collected for each of the worker replicates. The overall geometric means for hand exposure were 823, 21.0, 7.0, and 16.0 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 130, 311, and 285 μg/lb ai for pot men, spray men, and line tenders, respectively.

Versar calculated head/neck exposures based on head and neck pads collected from each of the worker replicates. The overall geometric means for head/neck exposure were 182, 552, 359, and 102 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 50.6, 1,940, and 266 μg/lb ai for pot men, spray men, and line tenders, respectively.

Inhalation exposures were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined from the amount of ZPT found in the air sampling tubes. The overall geometric means for inhalation exposure were 10.7, 113, 11.4,and 1.40 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 4.34, 184, and 26.2 μg/lb ai for pot men, spray men, and line tenders, respectively.

This study met most of the Group A, 875.1100 (dermal exposure - outdoor), 875.1300 (inhalation exposure - outdoor), and 875.1600 (application exposure monitoring data reporting) Guidelines. The major issues of concern are: (1) For Trial A, the test subjects wore work gloves, rather than chemical-resistant gloves while they worked. These gloves were made of heavy cotton knit with rubberized palms that appeared to be somewhat absorbent, according to the study author. As a result, subjects in this trial experienced the greatest hand exposures; (2) For laboratory fortifications, only 1 to 4 replicates were run for each fortification level per matrix, which varied among each trial. For field fortifications, only 3 replicates were run for each fortification level per matrix. The guidelines specify that at least 7 samples should be run for each fortification level; (3) Personal air sampling pumps were set to produce an airflow of 1.5 L/min., rather than 2.0 L/min. specified in the guidelines; **[EPA Note: The airflow requirement of 2.0 L/min is not applicable to this study because the analytical method had an adequate LOD with airflow used.]** and 4) Air sampling filters were capped and stored frozen in individually in a fresh, locking polyethylene storage bags prior to extraction. Heavy filter paper was not used **[EPA Note: The polyethylene bags are preferable to paper filters because they provide an airtight seal to prevent sample contamination]**.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1) (A), (B), or (C). The study sponsor and author stated that the study was conducted under EPA Good Laboratory Practice Standards (40 CFR part 160), with the following exceptions: 1) the quantities of test substance required to treat the commercial vessels could not be conveniently prepared, analyzed, and transported especially for this study; therefore, the test substance used consisted of lots of the antifouling paint that were onsite or delivered just prior to testing; 2) GLP-compliant data on test substance purity, expiration dates and other relevant characteristics were not available for the lots of test substance used in this study; 3) the test substance was delivered to each test site in large numbers of containers that could not be stored per 40 CFR §160.105(c); 4) one sample of each lot of the test substance was collected for archival storage and later analysis with the exception of the 2-gallon MICRON 66 Lot DK6602 used in Trial B; 5) The paint application equipment at each site was not configured to permit GLP-compliant calibration, and therefore, was not calibrated prior to each application of the test substance for this study. Instead, study personnel collected copies of measurements of the thickness of applied paint films at each trial; 6) subject body weights were obtained at each test site using commercial scales that were not calibrated per GLP; and 7) Two dataloggers used to record sample freezer

temperatures during Trial C were lost in transit from the test site; therefore, data they had retained were lost. The study author stated that none of the deviations had any significant impact on the results and validity of the study.

GUIDELINE: The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100 (dermal exposure - outdoor), 875.1300 (inhalation exposure - outdoor) and 875.1600 (Application exposure monitoring data reporting). A compliance checklist is provided in Appendix A.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

Each test substance (paint) was formulated with the manufacturing use product Zinc Omadine Power AF which contains 95% of the active ingredient, zinc pyrithione (zinc 2-pyridinethiol-1-oxide; ZPT). All paints used in the monitoring study were obtained from International Paint, Inc. The specific antifoulant paints used at each test site are detailed below:

Trials A and C:

Formulation:	Intersmooth 460 SPC Antifouling Paint
Product Codes:	BEA468 (brown) and BEA469 (red)
Nominal ai content:	3.80% ZPT by weight
Other Relevant Information:	EPA Reg. No.: 2693-187
	EPA Est. No.: 2693-NJ-1

Trial B:

Formulation:	Interlux Micron 66 Antifouling Paint
Product Codes:	YBA473 (black)
Nominal ai content:	3.80% ZPT by weight
Other Relevant Information:	EPA Reg. No.: 2693-187
	EPA Est. No.: 2693-NJ-1

Trial D:

Formulation:	Intersmooth 460 SPC Antifouling Paint
Product Codes:	BEA462 (blue)
Nominal ai content:	3.80% ZPT by weight
Other Relevant Information:	EPA Reg. No.: 2693-187
	EPA Est. No.: 2693-TX-1

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

According to the Study Report, the test products were Intersmooth 460 SPC Antifouling Paint (brown and red), Interlux Micron 66 Antifouling Paint (black), and Intersmooth 460 SPC Antifouling Paint (blue) containing 3.80% by weight of the active ingredient, zinc pyrithione (ZPT).

3. Packaging:

Intersmooth 460 SPC Antifouling Paints (BEA468 and BEA469) were packaged in 5-gallon cans; Interlux Micron 66 Antifouling Paint (YBA473) was packaged in 1-gallon cans; and Intersmooth 460 SPC Antifouling Paint (BEA462) was packaged in 20-L cans.

B. STUDY DESIGN

There were eight amendments to and twelve deviations from the study protocol. Detailed explanations of the changes can be found in the study report (pages 233-391). The study author stated that these changes did not appear to adversely affect the outcome of the study.

1. Number and type of workers and sites:

Based on preliminary studies by the Sponsor and observations of commercial ship hull painting operations by the Study Director, the following three positions were selected for exposure monitoring as representing those likely to experience the maximum exposure during ship hull painting: pot men (15 workers monitored), spray men (18 workers monitored), and line tenders (16 workers monitored). Each test subject in Trials B and C could be assigned to one of the individual positions; however, in Trials A and D, subjects often performed the tasks associated with multiple positions during each work cycle. Therefore, subjects in each work cycle of Trials A and D were identified for the purposes of the study according to the task on which they spent the majority of time during that work cycle. Specific details about each test subject was not provided.

The test sites used in the study were located at shipyards in Boston, Massachusetts (Trials A and D) and Freeport, Grand Bahama (Trials B and C). Each shipyard included a dry dock, in which the target ship was positioned for treatment; facilities for receiving and storing paint containers before use; roll-off trash containers for removal of empty paint cans; and a source of compressed air to operate paint application equipment. The layout of the shipyards are details in Figures 2 and 3 of the study report (pages 55-56).

The Boston shipyard contains a graving (excavated) dock built in 1908. The dry dock is 1176 ft long, 124 ft wide, and 44 ft deep. During treatment, each test vessel was supported on a series of approximately 4-ft high wood and concrete blocks, to allow the flat bottom portion of the vessel to be painted. To prevent escape of spray particles during the treatment process, personnel rigged cables from the sides of the dry dock to attachment points above the water line on each ship's hull, from which plastic sheets were suspended to partially isolate the hull portions being painted. The sheets did not extend to the floor and were not attached to one another along the vertical edges; therefore, a continuous breeze within the dock moved the sheets about, intermittently leaving large openings.

The Freeport facility includes a floating dry dock built in approximately 1971. The dry dock is 176 ft long and 52 ft wide, with 22-ft high side walls. This dock can be partially submerged to allow the ship to be treated to sail over the dock floor, after which it is refloated to raise the ship above the water level. During treatment, each test vessel was supported on a series of stacked wooden blocks to allow the flat bottom of the vessel to be painted. For Trial B, personnel rigged plastic sheeting from just above the waterline of the ship's hull to the floor of the dock, and taping adjacent sheets, sealing the area to be painted except for a small open flap serving as a door. An exhaust fan removed air from the treating area. For Trial C, no sheeting was applied to the treating area.

2. Meteorology:

During the study, personnel monitored and recorded test site outdoor air temperature, relative humidity, wind direction, wind speed, and cloud cover at 30 minute intervals using a calibrated hand-held Kestrel® 3000 weather meter at the field control sample site for each trial. Table 1 provides meteorological data pertinent to the study.

Table 1. Meteorological Data at Study Sites

Trial	Work Cycle	Location	Maximum Temperature (°F)	Minimum Temperature (°F)	Maximum Relative Humidity (%)	Minimum Relative Humidity (%)	Average Wind Direction (compass point)	Maximum Wind Speed (mph)
A	1	Dry dock[1]	56	52.3	47	29	W	7.1
		Field Spike Table	58.7	52.7	52	37	SE-NW	8.3
	2	Dry dock[1]	69	61.4	48	34	W	5.1
		Field Spike Table	66.9	58.4	52	36	E-NE	11.6
B	1	Field Spike Table	78.6	70.5	77	52	SE-NE	11.1
	2, 3	Field Spike Table	78.6	72.8	79	63	NE-SW	10.7
C	1, 2	Field Spike Table	77.3	66	68	42	SE-E	10.7
D	1	Field Spike Table	53.7	46.3	39	18	E	10.2
	2	Field Spike Table	66.7	53.4	57	24	E	5.2

[1] During Trial A, personnel collected weather data within the dry dock during treatment, this was not repeated for other trials, due to the difficulty of keeping sensors clear of paint particulates during application.

3. Replicates:

A total of 49 replicates were monitored over four trials consisting of 15 pot men, 18 spray men, and 16 line tenders. Each test subject in Trials B and C were assigned to one of the individual positions, however, in Trials A and D, subjects often performed the tasks associated with multiple positions during each work cycle. Therefore, subjects in each work cycle of Trials A and D were identified for the purposes of the study according to the task on which they spent the majority of time during that work cycle. The workers were monitored for 1-2 consecutive work cycles each over one or two test days. Treatment was conducted by airless spray guns without wands, fed by high-pressure hoses from compressed air-powered portable air pumps operating at 3,500-4,500 psi. The work cycle durations ranged from 57 minutes to 6 hours 52 minutes and the areas treated ranged from 5,000 to 27,604 ft^2. The pot men handled 9.82 to 19.22 lbs ai, line tenders were exposed to 5.97 to 24.36 lbs ai, and spray men applied 5.10 to 19.22 lbs ai.

4. Protective Clothing:

Workers wore a 100% polyester, whole-body dosimeter (WBD) consisting of a Medalist® #3500 long-sleeved undershirt and #5500 long pants. The WBD was worn under the test subjects' work clothing, which consisted of either a 100% cotton flannel shirt and 100% cotton jeans (Trial A), a 100% cotton short-sleeved work shirt and 100% cotton twill work pants (Trials B and C), or a 100% cotton tee shirt and 100% cotton jeans. A disposable Tyvek® hooded coverall was worn over the workers' clothing. In addition, workers wore a pair of dosimeter gloves custom-manufactured from Medalist R-29 polyester fabric under either work gloves (Trial A) or Ansell #97-600 gauntlet-style nitrile chemical resistant gloves (Trials B-D).

5. Monitored Positions:

Pot Men.
Moved the formulated test substance from the storage area to the mixing/loading site, mixed the test substance and loaded it into the spray equipment, operated spray equipment and performed maintenance as required, cleaned the spray system at the end of the work cycle, handled used test substance containers.

Spray Men:
Prepared, cleaned, and operated spray guns to apply the formulated test substance; operated the mobile access platform when necessary to move from work site to work site; cleaned the spray gun at the end of the work cycle.

Line Tenders:
Performed tasks such as feeding hoses from the applicator unit to the spray men; freeing hoses caught on debris or equipment; carrying portable electric lights to illuminate areas to be sprayed; operating the mobile access platform for the spray men; fetching cans of the test substance for the pot men; and/or clearing debris and unused equipment from the work sites.

6. **Application Rate:**

The formulated test substance used for each trial consisted of cans of commercial antifoulant paint. For Trial A, the test substance consisted of lots of Intersmooth 460 SPC Antifouling (33 5-gallon cans of dark brown on Day 1, and 29 cans of dark red on Day 2), applied to a cruise ship. In Trial B, a privately-owned megayacht was treated using lots of Micron 66 (98 1-gallon cans), a formulation essentially identical to the SPC products in ZPT content, but with a slightly different solvent system. Trial C utilized only SPC dark brown (10 5-gallon cans), applied to the hull of a commercial cargo vessel. For Trial D, a portion of the hull of another cruise ship was painted with SPC dark blue (15 20-L cans).

In lieu of applying analyzed lots of the formulated test substance to each test ship, study personnel weighed each container before and after use, and calculated the quantity used during each work cycle based on those weights. To determine the quantity of ZPT applied during each replicate, study personnel collected samples of each lot of paint used at each site and analyzed the samples for ZPT concentrations. The mean ZPT concentrations of the lots applied in Trials A, B, C and D were 3.70%, 3.53%, 3.58%, and 4.04%, respectively. The total ZPT applied in Trials A, B, C, and D was 147 lbs., 47.1 lbs., 20.4 lbs., and 34.0 lbs, respectively.

7. **Exposure monitoring methodology:**

Inner Dermal Dosimeters: Inner whole body dosimeters consisted of a 100% polyester, Medalist® #3500 long-sleeved undershirt and #5500 long pants. These were worn directly underneath the outer clothing and Tyvek coverall. At the end of the monitoring period, the inner dosimeters were carefully removed in a designated preparation area, which was lit only with incandescent lamps to minimize photodegradation of ZPT on the exposed matrices. Study personnel helped the test subject remove and place the whole body dosimeter on a non-contaminated surface for processing. The study personnel cut the dosimeter top along the shoulder seams to produced a sleeve pair and a torso top. The dosimeter bottom was folded in half lengthwise, and cut at the crotch to produce a leg pair and a torso bottom. The scissors were rinsed in fresh 30:70 DMSO:acetone and dried with a fresh paper towel before cutting.

Each arm pair, leg pair, torso top, and torso bottom were placed into individual polyethylene storage bags, labelled, and placed inside a second locking storage bag. All the samples were placed into a 1,000-lb. capacity plastic cooler with dry ice (Trials A and D) or in an electric chest freezer (Trials B and C) operating at <0°C prior to shipment to the analytical laboratory.

Head and Neck Pads: Head and neck pads consisted of a 4 inch x 4 inch piece of Medalist R-29 polyester fabric stapled to a backing sheet of glassine. One pad was pinned to the front of the coverall and the other was fastened to the rear of the work shirt just below the neck opening, representing uncovered face and neck front, and covered head and back, respectively. The patches were exposed facing out. At the end of the monitoring period, the pads were removed from the worker by study personnel wearing fresh disposable gloves. The pads were placed into individual polyethylene storage bags, labelled, and placed inside a second locking storage bag. All the samples were placed into a 1,000-lb. capacity plastic

cooler with dry ice (Trials A and D) or in an electric chest freezer (Trials B and C) operating at <0°C prior to shipment to the analytical laboratory.

Gloves: Prior to each work period, the workers washed their hands with soap, rinsed with distilled water, and then dried them with fresh paper towels before putting on the dosimeter gloves. These gloves were custom-manufactured from Medalist R-29 polyester fabric and were worn under either work gloves (Trial A) or Ansell #92-600 gauntlet-style nitrile chemical resistant gloves (Trials B-D). At the end of the monitoring period, the gloves were removed from the worker by study personnel wearing fresh disposable gloves. The pads were placed into individual polyethylene storage bags, labelled, and placed inside a second locking storage bag. All the samples were placed into a 1,000-lb. capacity plastic cooler with dry ice (Trials A and D) or in an electric chest freezer (Trials B and C) operating at <0°C prior to shipment to the analytical laboratory.

Inhalation: Air concentrations of ZPT were monitored in the worker's breathing zone using a personal air sampler (Omega Specialty Instrument Co NS-FPL033750MC or equivalent) consisting of a 37-mm binder-free glass fiber filter in an opaque, conductive polypropylene cassette attached to the front of the coverall as close to the breathing zone as possible with the intake facing downward. The outlet end was connected to a second cassette containing a mixed cellulose ester filter (for back pressure maintenance only), then by Tygon® and vinyl tubing to a Buck Model S.S.™ air sampling pump worn on the worker's belt, outside the Tyvek coverall. For Trial A, the sampling pump was worn inside the coverall, and the air sampler's Tygon hose protruded through a small slit cut in the fabric of the coverall ans sealed with duct tape to prevent contamination. The pump operated at a flow rate of 1.5 liters per minute. The flow rates were calibrated at the beginning and end of each exposure period.

At the end of the monitoring period, the air pumps were turned off and removed by study personnel wearing fresh disposable gloves. They recorded the stop time, removed the sampling train, determined and recorded the pump's flow rate, and recorded the screen-displayed battery level and sampled volume. The air sampling cassettes were capped, placed into individual polyethylene storage bags, labelled, and placed inside a second locking storage bag. All the samples were placed into a 1,000-lb. capacity plastic cooler with dry ice (Trials A and D) or in an electric chest freezer (Trials B and C) operating at <0°C prior to shipment to the analytical laboratory.

Field monitoring was conducted on November 6-7, 2004 for Trial A, on January 4-5, 2005 for Trial B, on February 9, 2005 for Trial C, and on April 16-17, 2005 for Trial D. For Trial A, samples were received by the analytical lab on November 9, 2004. The time from sample collection to extraction ranged from 10 to 29 days. For Trial B, samples were received by the analytical lab on January 13, 2005. The time from sample collection to extraction ranged from 13 to 20 days. For Trial C, samples were received by the analytical lab on February 15, 2005. The time from sample collection to extraction ranged from 19 to 21 days. For Trial D, samples were received by the analytical lab on April 18, 2005. The time from sample collection to extraction ranged from 26 to 48 days.

8. Analytical Methodology:

Extraction method(s): Inner Dosimeters – Dosimeter sections were placed into a 2.5-L amber wide mouth bottle. Appropriate amounts of 30:70 DMSO:Acetone extraction solvent was added to the bottle (see Table below), the bottle was capped with a PTFE-lined lid and shaken for 30 minutes at room temperature. An appropriate amount of the derivatizing solution, containing 50 ppm monobromobimane (MBB), 2000 ppm EDTA and 5% acetonitrile in water, was added to the extraction bottle (see Table below). The samples were shaken for an additional 20 minutes to complete the derivatization. An aliquot of the extract was collected for HPLC analysis.

WBD Section	Extraction Solvent (mL) (30:70 DMSO:Acetone)	Derivatizing Solution (mL) "DSM"
Torso	900	1350
Divided Pieces of Torso Top	600	900
Arm Pairs	800	1200
Torso Bottom	800	1200
Leg Pairs	800	1200

Head and Neck Pads – The pad was placed in an 2-oz. amber glass bottle. Thirteen mL of the 30:70 DMSO:Acetone extraction solvent was added to the bottle, the bottle was capped with a Teflon-lined lid and shaken for 30 minutes at room temperature. Twenty mL of the derivatizing solution, containing 50 ppm monobromobimane (MBB) and 2000 ppm EDTA, was added to the extraction bottle. The samples were shaken for an additional 20 minutes to complete the derivatization. The sample was filtered and an aliquot of the extract was collected for HPLC analysis.

Dosimeter Gloves – The glove pair was placed in an 8-oz amber glass bottle. The DMSO:Acetone extraction solvent was added (160 mL) to the bottle, the bottle was capped with a Teflon-lined lid and shaken for 30 minutes at room temperature. Derivatizing solution, containing 50 ppm monobromobimane (MBB) and 2000 ppm EDTA, was added (240 mL) to the extraction bottle. The samples were shaken for an additional 20 minutes to complete the derivatization. The sample was filtered and an aliquot of the extract was collected for HPLC analysis.

Air Sampling Filters – The air filter was removed from its cassette, separated from the support pad and placed in an amber 2-oz. glass bottle. Thirteen mL of the 30:70 DMSO:Acetone extraction solvent was added to the bottle, the bottle was capped with a Teflon-lined lid and shaken for 30 minutes at room temperature. Twenty mL of the derivatizing solution, containing 50 ppm monobromobimane (MBB) and 2000 ppm EDTA, was added to the extraction bottle. The samples were shaken for an additional 20 minutes to complete the derivatization. The sample was filtered and an aliquot of the extract was collected for HPLC analysis.

Detection method(s): Inner dosimeter extract solutions were analyzed by a High Performance Liquid Chromatography (HPLC) system with an autosampler, column temperature controller and fluorescence detector (FD). Head/neck pads, gloves, and air sampling filters were analyzed by a Waters Alliance 2695 HPLC system or equivalent equipped with a Waters 474 or 2475 fluorescence detector. Tables 2 and 3 provide a summary of the chromatographic conditions.

Table 2. Summary of HPLC Operating Conditions
Pharmalytica Services Method – Inner Dosimeters

Column	MacMod HydroBond AQ, 2.1 x 50 mm, 3 µm pre-column coupled with a 2.1 x 250 mm, 5 µm column
Column Temperature	40°C
Flow Rate	0.2 mL/min. – 0.4 mL/min.
Injection Volume	5µL
Fluorescence Detector	Excitation: 380 nm Emission: 480 nm Bandwidth: 10 nm Gain: 10-100 (depending on detector make and model)
Run Time	35 minutes
Injector Washing Solution	50% Methanol/50% Water

Mobile Phases	A: 15% Acetonitrile/85% Water B: Acetonitrile		
	Time (min.)/Flow Rate	%A	%B
	0.00/0.2	100	0
	21.0/0.2	100	0
	21.1/0.4	6	94
	24.0/0.4	6	94
	24.1/0.4	100	0
	29.0/0.4	100	0
	30.0/0.2	100	0
	35.0/0.2	100	0

Table 3. Summary of HPLC Operating Conditions
Arch Method – Head/Neck Pad, Gloves, Air Sampling Filter

Column	MacMod HydroBond AQ (2.1 x 250 mm, 5 µm particle size) with a 2.1 x 50 mm (3 µm particle size) HydroBond AQ column as a pre-column		
Injection Volume	5µL		
Detection Settings	Excitation: 380 nm Emission: 480 nm Bandwidth: 10 nm Gain: 25 for 2475 and 1000 for 474 detector		
Run Time	30 minutes		
Injector Washing Solution	50% Methanol/50% Water		
Mobile Phases	A: Acetonitrile B: Water		
	Time (min.)/Flow Rate	%A	%B
	0.00/0.2	15	85
	21.0/0.2	15	85
	21.1/0.4	95	5
	24.0/0.4	95	5
	24.1/0.4	15	85
	24.0/0.4	15	85
	24.1/0.4	15	85
	29.0/0.4	15	85
	29.1/0.2	15	85
	30.0/0.2	15	85

Method validation: Two methods were used for the determination of ZPT in the monitored matrices. Arch's Method (TSOP065), "Determination of Zinc Pyrithione in Exposure Monitoring Matrices by High Performance Liquid Chromatography" was used for analysis of ZPT in head/neck pads, gloves, and air sampling filter samples. Pharmalytica Services' Method (C016-MET-018.03), "Determination of Zinc Pyrithione in Exposure Monitoring Matrices by HPLC-FD" was used for analysis of ZPT in whole body dosimeter matrices.

These two methods were validated at Arch and Pharmalytica to obtain the parameters including accuracy, precision, specificity, linearity, limit of detection (LOD), and limit of quantitation (LOQ). For each matrix, seven replicate samples were fortified at 1x LOQ 10x LOQ, and 150x LOQ prior to the start of the study. Additional spikes were made at 4000x LOQ, 6000x LOQ, 12,400x LOQ, and 140,000x LOQ for dermal patches, 170,000x LOQ for glove pairs, and 6,000x LOQ for air filter membranes after sample analysis, to obtain recoveries when high levels of ZPT were found in the field samples. Recoveries of ZPT from the fortified samples ranged from a mean value of 72.9% to 99.7% for WBD sections, 45.3% to 98.2% for dermal patches, 74.8% to 114% for glove pairs, and 90.1% to 101.3% for air sampling filters. These results demonstrated the adequacy of the methods for determination of ZPT on the dermal and inhalation media to be used in the field testing. ZPT levels in the control samples were all <LOD.

The limit of quantification (LOQ) was 0.200 µg/sample for the air sampling filter and head/neck pads, 2.40 µg/sample for the glove pair, and 10.0 for the whole body dosimeter sections. The limit of detection (LOD) was 0.060 µg/sample for the air sampling filter and head/neck pads, 0.70 µg/sample for the glove pair, and 4.0 for the whole body dosimeter sections.

Instrument performance and calibration: Two quality control standards in the mid-range of the calibration curve were run after every 10 samples to assess the accuracy of the instrument calibration.

Quantification: The calibration curve was established by plotting ZPT concentrations of the standards in ng/mL against the peak area counts of the derivatized ZPT peak. A linear regression analysis was applied to the data to obtain slope, intercept, error of intercept, and correlation coefficient of the curve. In order to improve the accuracy of the analysis, the calibration curve was divided into two ranges to bracket the concentration of ZPT in solution. The lower range curve included the ZPT standards with concentrations ranging from approximately 2 ppb to 50 ppb. The higher range curve included ZPT standards with concentrations ranging from approximately 50 ppb to 4 ppm.

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

Lab Recovery: Method blanks, matrix blanks, and matrix spikes were routinely analyzed to document the validity of data and to control data quality with acceptance limits. Method blanks were analyzed at the beginning and end of a batch analysis to assess possible contamination from the laboratory. One matrix blank was analyzed at the beginning of a batch run following a method blank. Fresh matrix spikes fortified at 2x LOQ and 150x LOQ were prepared and analyzed along with the field samples.

Overall fortified laboratory recoveries ranged from 103.3% (whole body dosimeters) to 108.4% (air filters). Table 4 provides a summary of the overall average recoveries for each matrix at each fortification level.

Table 4. Summary of Laboratory Fortified Sample Recoveries for All Matrices

Matrix	Trial	Fortification Rate	Mean (%)	Std. Dev. (%)	Trial Mean (%)	Trial Std. Dev. (%)	Overall Mean (%)	Overall Std. Dev. (%)
WBD Sections	A	2x LOQ	78.3	26.9	92.6	23.4	103.3	28.2
		150x LOQ	106.9	3.3				
	B	2x LOQ	90.4	9.6	92.6	8.9		
		150x LOQ	94.8	8.9				
	C	2x LOQ	119.2	N/A	113.2	8.5		
		150x LOQ	107.2	N/A				
	D	2x LOQ	145.2	44.9	122.2	38.8		
		150x LOQ	99.1	8.8				
Head/Neck Pads	A	2x LOQ	128.9	N/A	117.8	15.7	103.8	14.4
		150x LOQ	106.7	N/A				
	B	2x LOQ	82.5	2.3	93.8	13.4		
		150x LOQ	105.2	4.5				
	C	2x LOQ	122.0	N/A	113.6	11.8		
		150x LOQ	105.2	N/A				
	D	2x LOQ	110.7	5.1	101.8	10.8		
		150x LOQ	92.8	2.6				
Air Sampling Filter	A	2x LOQ	124.7	2.3	113.9	12.7	108.4	19.6
		150x LOQ	103.1	2.9				
	B	2x LOQ	65.9	N/A	86.4	28.9		
		150x LOQ	106.8	N/A				
	C	2x LOQ	136.1	N/A	124.3	16.7		
		150x LOQ	112.6	N/A				
	D	2x LOQ	113.6	N/A	103.5	14.3		
		150x LOQ	93.4	N/A				
Glove Pair	A	2x LOQ	106.9	0.1	103.4	4.8	106.4	11.0
		150x LOQ	99.9	4.5				
	B	2x LOQ	91.9	N/A	97.2	7.5		
		150x LOQ	102.5	N/A				
	C	2x LOQ	127.0	N/A	118.7	11.7		
		150x LOQ	110.4	N/A				
	D	2x LOQ	121.7	N/A	109.2	17.7		
		150x LOQ	96.7	N/A				

Field blanks: On each day of monitoring, three unfortified control samples per set of each matrix were prepared. For Trial A, the samples were set up and exposed on tables located in the parking lot of the property immediately North or the Northwest corner of the yard, slightly West of the West end of the dry dock. For Trial D, tables were set up with the shipyard property, either in the Northwest corner (day 1) or the Southeast corner (day 2). Each location was approximately 300 feet upwind from the nearest portion of the test vessel. For Trials B and C, samples were set up and exposed on tables located in a covered area 300 ft. Southeast of the East end of the dry dock. It was not clear if the locations used for the untreated field controls were the same locations where the field fortification monitoring took place.

Field recovery: Field fortification was performed on each day of monitoring. Six whole body dosimeter sections, six head/neck pads, and six air samplers were prepared. The study authors note that the field fortification head/neck pad samples were to be representative of the inner glove dosimeters as well. Three samples of each matrix were spiked at 2X LOQ and three samples were spiked at 150X LOQ. Samples were spiked in the Arch Chemicals, Inc. laboratory, bagged, labelled and frozen as soon as possible after spiking was completed. The field spikes were shipped to the field site by priority overnight courier service.

On each day of monitoring, the dermal field spikes were removed from their bags and laid out on a surface covered with fresh polyethylene trash bags, arranging and folding them to shade their fortified surfaces and prevent cross-contamination, exposing them to ambient conditions for the maximum duration of a work cycle. The samples were secured to the table with solvent-rinsed metal push pins. Air samplers were unwrapped, and connected to a pre-calibrated personal air sampling pump operating at 1.5 L/min. for the maximum duration of a work cycle. At the end of the exposure period, the samples were bagged, labelled, and stored frozen until shipment to the analytical laboratory.

The overall average field fortification recoveries ranged from 84.3% (WBD, day 1) to 118.1% (Head/Neck Pads, day 1) for Trial A, ranged from 87.8% (WBD, day 2) to 109.0% (Head/Neck Pads, day 1) for Trial B, ranged from 112.3% (WBD) to 123.5% (Air sampling filters) for Trial C, and ranged from 93.0% (WBD, day 1) to 129.01% (WBD, day 2). Table 5 provides a brief summary of the field fortification recoveries.

Formulation: Field fortification samples were spiked using the paint formulation associated with the given trial.

Tank mix: Not applicable to this study.

Travel Recovery: Travel recovery samples were not discussed in the study report.

Storage Stability: The stability of ZPT residues was determined in triplicate sets of head/neck pads, representing all fabric media, and air sampling filters stored frozen for up to 56 days after fortification with control paint containing ZPT at 2x, 50x, and 150x LOQ. Samples were analyzed after 7, 14, 21, 28 and 56 days of frozen storage. For the head/neck pads, the average recoveries were 85.1% (2x LOQ), 96.7% (50x LOQ) and 89.9% (150x LOQ) after 56 days of frozen storage. For the air sampling filters, the average recoveries were 99.0% (2x LOQ), 90.4% (50x LOQ), and 93.0% (150x LOQ) after 56 days of frozen storage.

Table 5. Field Fortification Recovery Results From Exposure Monitoring Matrices.

Trial	Test Day	Matrix	Spike Rate	Mean (%)	Std. Dev. (%)	Overall Mean (%)	Overall Std. Dev. (%)
A	1	Whole Body Dosimeter	2x LOQ	63.7	11.0	84.3	23.7
			150x LOQ	105.0	1.8		
		Head/Neck Pads	2x LOQ	129.6	1.1	118.1	12.5
			150x LOQ	106.7	0.79		
		Air Sampling Filters	2x LOQ	127.6	5.8	113.6	15.9
			150x LOQ	99.5	1.1		
	2	Whole Body Dosimeter	2x LOQ	79.8	15.0	88.8	13.7
			150x LOQ	97.8	1.3		
		Head/Neck Pads	2x LOQ	120.0	1.8	112.9	7.9
			150x LOQ	105.9	0.99		
		Air Sampling Filters	2x LOQ	120.6	3.1	107.7	14.2
			150x LOQ	94.9	0.8		
B	1	Whole Body Dosimeter	2x LOQ	103.2	7.6	104.2	4.9
			150x LOQ	105.2	0.5		
		Head/Neck Pads	2x LOQ	123.3	8.9	109.0	16.6
			150x LOQ	94.7	0.88		
		Air Sampling Filters	2x LOQ	118.5	2.9	105.4	14.5
			150x LOQ	92.3	1.9		
	2	Whole Body Dosimeter	2x LOQ	80.5	3.7	87.8	8.4
			150x LOQ	95.2	1.1		
		Head/Neck Pads	2x LOQ	120.7	6.9	104.7	18.2
			150x LOQ	88.7	3.99		
		Air Sampling Filters	2x LOQ	116.8	0.6	104.5	13.6
			150x LOQ	92.1	1.2		
C	1	Whole Body Dosimeter	2x LOQ	126.2	3.3	112.6	14.9
			150x LOQ	99.1	0.5		
		Head/Neck Pads	2x LOQ	119.7	2.3	112.3	8.2
			150x LOQ	105.0	0.59		
		Air Sampling Filters	2x LOQ	133.3	2.7	123.5	10.9
			150x LOQ	113.6	0.4		
D	1	Whole Body Dosimeter	2x LOQ	100.5	1.9	93.0	8.4
			150x LOQ	85.5	1.8		
		Head/Neck Pads	2x LOQ	111.1	3.7	99.1	13.3
			150x LOQ	87.2	1.78		
		Air Sampling Filters	2x LOQ	113.3	5.6	103.2	11.7
			150x LOQ	93.1	1.3		
	2	Whole Body Dosimeter	2x LOQ	151.2	51.6	129.0	41.0
			150x LOQ	106.8	7.8		
		Head/Neck Pads	2x LOQ	111.0	1.5	99.6	12.6
			150x LOQ	88.1	0.74		
		Air Sampling Filters	2x LOQ	92.2	11.7	95.8	9.3
			150x LOQ	99.3	6.4		

10. Relevancy of Study to Proposed Use:

The study design and the proposed uses for this chemical are similar.

II. RESULTS AND CALCULATIONS:

The Registrant provided dermal and inhalation exposure values expressed as μg/lbs ai handled and μg/kg body weight/lbs ai handled. The Registrant corrected the raw field data based on average field fortification recoveries of the appropriate matrix exposed in the field on the same day. Recoveries from the head/neck pad field fortification samples were used to correct inner glove samples. Adjustments were not made when recoveries from the field control samples were >100%. Inhalation exposures were normalized for the pump flow rate of 1.5 L/min. to a breathing rate of 1,500 L/hr for moderate activities, then by adjustment for standard worker body weight (70 kg).

The final report does not include data for replicates 41 and 51 (replicates from Trial D). It is unclear why this is the case; the analytical report shows that dermal and inhalation samples for these two replicates were analyzed. Versar estimated exposures based on the data presented by the registrant (i.e., without replicates 41 and 51).

Versar estimated dermal and inhalation exposure values as μg/lb ai handled. The method of correcting for field fortification sample recoveries was similar to the method used by the registrant. Average field fortification recoveries, calculated by fortification level and matrix from each trial separately, were used to adjust the field residues if the recoveries were less than 90%. To calculate the inhalation exposures, Versar adjusted the flow rate of each worker by an average breathing rate of 0.0167 m^3/min for light activities, which is the inhalation rate recommended for use by NAFTA for light activity.

Versar used the Shapiro-Wilks test on both non-transformed and log-transformed data to test for normality and lognormality, respectively (tested for $p \geq 0.05$ and $p \geq 0.01$). These tests were conducted for total dermal exposure (expressed in terms of ug/lb ai). Initially, data sets were separated by trial and by job function. At the $p \geq 0.05$ significance level, significant non-normality was found in only two datasets (Trial B line tenders and Trial D line tenders) and significant non-lognormality was found in only one dataset (Trial D line tenders). However, because the datasets were small at this level of grouping ($2 \leq N \leq 6$), extreme deviations in the observations would be necessary for significant non-normality or non-lognormality to be detected. Therefore, the data were grouped into larger sets for further testing. When the data were grouped by job function across all trials, significant non-normality was found for all jobs, and no significant non-lognormality was found at the $p \geq 0.05$ significance level. At the $p \geq 0.01$ significance level, line tenders and pot men showed significant non-normality, and none of the job functions showed significant non-lognormality. These results suggest that the data for a given job function are lognormally distributed. When the data were grouped for each trial across all job functions, significant non-normality was found for all trials, and no significant non-lognormality was found at the $p \geq 0.05$ significance level. At the $p \geq 0.01$ significance level, trials B, C, and D showed significant non-normality, and none of the trials showed significant non-lognormality. These results suggest that the data for a given trial are lognormally distributed. Therefore, the appropriate measure of central tendency for data grouped by job function or by trial is the geometric mean.

Exposure values were summarized two ways: by trial and by job function. When summarizing exposures over a single trial, it was assumed that the job functions performed by the replicates were representative of the type of work typically performed in painting operations, and that the work was divided in a representative fashion. Therefore, the geometric mean was taken over all workers. When summarizing exposures for a given job function over all trials, it was assumed that each trial had equal weight, regardless of the number of replicates monitored for each trial. Therefore, for a given job function, four geometric means were calculated (one for each trial) and the arithmetic mean of the four geometric means was calculated as a summary statistic.

Total Dermal Exposures (Including Hands, Face, Neck)

Dermal exposure was estimated by measuring residues on or in inner whole body dosimeters, head/neck pads, and dosimeter gloves. Tables 6-10 provide the Versar-calculated dermal exposures for each of the four trials. Total dermal exposures ranged from 385 μg/lb ai handled (pot man) to 5,150 μg/lb ai handled (spray man) for worker replicates at Trial A; ranged from 115 μg/lb ai handled (pot man) to 19,500 μg/lb ai handled (line tender) for worker replicates at Trial B; ranged from 226 μg/lb ai handled (pot man) to 4,410 μg/lb ai handled (spray man) for worker

replicates at Trial C, and ranged from 16 μg/lb ai handled (pot man) to 3,412 μg/lb ai handled (spray man) for worker replicates at Trial D.

The overall geometric means for total dermal exposure were 1,410, 1,530, 639, and 177 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 284, 2,904, and 1,030 μg/lb ai for pot men, spray men, and line tenders, respectively.

It should be noted that the values presented are not baseline values, but exposure values with personal protective equipment (PPE) as the workers wore a Tyvek coverall over their work clothes.

Hand Exposures

Versar calculated hand exposures based on dosimeter gloves collected for each of the worker replicates. Tables 11-15 provide the Versar-calculated dermal exposures for each of the four trials. Worker hand exposures ranged from 178 μg/lb ai handled (pot man) to 4,330 μg/lb ai handled (line tender) at Trial A, ranged from 0.12 μg/lb ai handled (pot man) to 206 μg/lb ai handled (spray man) at Trial B, ranged from 0.60 μg/lb ai handled (pot man) to 38 μg/lb ai handled (spray man) at Trial C, and ranged from 1.1 μg/lb ai handled (pot man) to 225 μg/lb ai handled (spray man) at Trial D.

The overall geometric means for hand exposure were 823, 21.0, 7.0, and 16.0 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 130, 311, and 285 μg/lb ai for pot men, spray men, and line tenders, respectively.

Head/Neck Exposures

Versar calculated head/neck exposures based on head/neck pads collected from each of the worker replicates. These are reported in Tables 16-20. Worker head/neck exposures ranged from 41 μg/lb ai handled (pot man) to 2,190 μg/lb ai handled (spray man) at Trial A, ranged from 16 μg/lb ai handled (pot man) to 19,100 μg/lb ai handled (line tender) at Trial B, ranged from 80 μg/lb ai handled (pot man) to 4,210 μg/lb ai handled (spray man) at Trial C, and ranged from 13 μg/lb ai handled (pot man) to 3,250 μg/lb ai handled (spray man) at Trial D.

The overall geometric means for head/neck exposure were 182, 552, 359, and 102 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 50.6, 1,940, and 266 μg/lb ai for pot men, spray men, and line tenders, respectively.

Inhalation Exposures

Inhalation exposures were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined from the amount of ZPT found in the air sampling filter. The personal monitoring pumps were set to an airflow of 1.5 L/min. The Registrant normalized inhalation exposures for the pump flow rate of 1.5 L/min. to a breathing rate of 1,500 L/hr for moderate activities, then by adjustment for standard worker body weight (70 kg). Versar used the NAFTA recommended inhalation rate of 0.0167 m^3/min for light activities.

Tables 21 through 25 provide the Versar-calculated potential inhalation exposures. Worker inhalation exposures ranged from 2.1 μg/lb ai handled (pot man) to 116 μg/lb ai handled (line tender) at Trial A, ranged from 8.3 μg/lb ai handled (pot man) to 1,256 μg/lb ai handled (spray man) at Trial B, ranged from 4.1 μg/lb ai handled (pot man) to 50 μg/lb ai handled (spray man) at Trial C, and ranged from 0.1 μg/lb ai handled (pot man) to 29 μg/lb ai handled (spray man) at Trial D.

The overall geometric means for inhalation exposure were 10.7, 113, 11.4,and 1.40 μg/lb ai for Trials A, B, C, and D, respectively. The overall arithmetic means of the geometric means for each job function were 4.34, 184, and 26.2 μg/lb ai for pot men, spray men, and line tenders, respectively.

III DISCUSSION

A. LIMITATIONS OF THE STUDY:

This study met most of the Group A, 875.1100 (dermal exposure -outdoor), 875.1300 (inhalation exposure - outdoor), and 875.1600 (application exposure monitoring data reporting) Guidelines. The major issues of concern are: (1) For Trial A, the test subjects wore work gloves, rather than chemical-resistant gloves while they worked. These gloves were made of heavy cotton knit with rubberized palms that appeared to be somewhat absorbent, according to the study author. As a result, subjects in this trial experienced the greatest hand exposures; (2) For laboratory fortifications, only 1 to 4 replicates were run for each fortification level per matrix, which varied among each trial. For field fortifications, only 3 replicates were run for each fortification level per matrix. The guidelines specify that at least 7 samples should be run for each fortification level; (3) Personal air sampling pumps were set to produce an airflow of 1.5 L/min., rather than 2.0 L/min. specified in the guidelines; and 4) Air sampling filters were capped and stored frozen in individually in a fresh, locking polyethylene storage bags prior to extraction. Heavy filter paper was not used.

The final report does not include data for replicates 41 and 51(replicates from Trial D). It is unclear why this is the case; the analytical report shows that dermal and inhalation samples for these two replicates were analyzed.

B. CONCLUSIONS:

Dermal and inhalation exposure of dry dock workers classified as pot men, spray men and line tenders were determined in this study. Overall, the pot men received the lowest dermal and inhalation exposure across all four trials. The spray men received the overall highest dermal and inhalation exposure, with the exception of Trial A where the line tenders exposure values were consistently higher than the other three trials.

Table 6. Total Dermal Exposure (Including Hands, Face/Neck) for Trial A (μg/lb ai handled)

Replicate	Major Position	Total Inner Dermal Dosimeter (ug/sample)[a]	Head/Neck Pads (ug/sample)	Total Dosimeter Gloves (ug/sample)	Total Potential Dermal Residue (ug/sample)[b]	lbs ai handled	Total Potential Dermal Exposure (ug/lb ai handled)[c]
1	Spray Man	4,750	2,570	66,500	73,900	39.2	1,880
2	Line Tender	3,710	13,600	11,100	28,400	9.50	2,990
3	Line Tender	6,200	14,500	10,100	30,800	24.4	1,260
4	Line Tender	3,600	7,280	4,880	15,800	9.50	1,660
5	Pot Man	1,200	1,910	15,400	18,500	38.0	487
6	Spray Man	6,830	2,980	13,600	23,400	38.0	617
7	Pot Man	969	1,600	67,000	69,600	39.2	1,780
8	Pot Man	3,080	5,080	20,800	28,900	39.2	738
9	Spray Man	5,760	11,800	8,870	26,400	20.3	1,300
10	Spray Man	3,730	4,360	29,700	37,800	12.7	2,980
11	Pot Man	5,340	3,050	7,230	15,600	40.6	385
12	Line Tender	5,730	10,500	29,800	46,000	20.3	2,270
13	Spray Man	7,840	1,390	19,000	28,200	29.2	967
14	Pot Man	2,950	1,320	16,000	20,300	29.2	694
15	Spray Man	7,720	16,500	14,500	38,600	7.50	5,150
16	Line Tender	2,270	922	88,000	91,200	20.3	4,490
Overall Average							1,850
Overall Geomean							1,410
Overall Standard Deviation							1,420
CV (%)							77.0

a Inner dosimeter values represent dermal exposure while wearing personal protective equipment (PPE) as all workers wore a Tyvek coverall over their work clothes.

b Total Potential Dermal Residue = inner dosimeter residues + head/neck residues + glove residues

c Total Potential Dermal Exposure (μg/lb ai handled) = Total Dermal Residue (μg) /lb ai handled

Table 7. Total Dermal Exposure (Including Hands, Face/Neck) for Trial B (μg/lb ai handled)

Replicate	Major Position	Total Inner Dermal Dosimeter (ug/sample)[a]	Head/Neck Pads (ug/sample)	Total Dosimeter Gloves (ug/sample)	Total Potential Dermal Residue (ug/sample)[b]	lbs ai handled	Total Potential Dermal Exposure (ug/lb ai handled)[c]
17	Line Tender	2,110	1,110	252	3,480	8.95	388
18	Spray Man	8,860	75,400	1,440	85,700	6.97	12,300
19	Spray Man	35,900	55,800	569	92,200	10.9	8,460
20	Line Tender	5,190	2,060	1,070	8,320	8.95	929
21	Pot Man	2,460	481	42.0	2,990	17.9	167
22	Spray Man	5,050	43,700	525	49,300	9.83	5,020
23	Pot Man	1,700	270	2.00	1,970	17.2	115
24	Line Tender	2,930	662	183	3,770	8.60	439
25	Line Tender	3,160	165,000	172	168,000	8.60	19,500
26	Spray Man	6,350	42,400	1,440	50,200	7.38	6,800
27	Spray Man	4,270	42,100	511	46,900	6.85	6,840
28	Line Tender	3,190	252	74.0	3,510	5.97	588
29	Line Tender	4,300	6,940	112	11,300	5.97	1,900
30	Pot Man	1,850	226	8.00	2,080	11.9	175
31	Spray Man	4,920	4,820	617	10,400	5.10	2,030
Overall Average							**4,380**
Overall Geomean							**1,530**
Overall Standard Deviation							**5,630**
CV (%)							**129**

a Inner dosimeter values represent dermal exposure while wearing personal protective equipment (PPE) as all workers wore a Tyvek coverall over their work clothes.

b Total Potential Dermal Residue = inner dosimeter residues + head/neck residues + glove residues

c Total Potential Dermal Exposure (μg/lb ai handled) = Total Dermal Residue (μg) /lb ai handled

Table 8. Total Dermal Exposure (Including Hands, Face/Neck) for Trial C (μg/lb ai handled)

Replicate	Major Position	Total Inner Dermal Dosimeter (ug/sample)[a]	Head/Neck Pads (ug/sample)	Total Dosimeter Gloves (ug/sample)	Total Potential Dermal Residue (ug/sample)[b]	lbs ai handled	Total Potential Dermal Exposure (ug/lb ai handled)[c]
32	Pot Man	1,530	1,090	115	2,740	9.82	279
33	Line Tender	2,740	2,310	17.0	5,070	9.82	517
34	Spray Man	1,620	41,300	370	43,300	9.82	4,410
35	Spray Man	2,660	12,400	86.0	15,100	10.6	1,430
36	Pot Man	1,540	845	6.00	2,390	10.6	226
37	Line Tender	1,050	2,190	277	3,520	10.6	332
Overall Average							1,200
Overall Geomean							639
Overall Standard Deviation							1,640
CV (%)							136

a Inner dosimeter values represent dermal exposure while wearing personal protective equipment (PPE) as all workers wore a Tyvek coverall over their work clothes.

b Total Potential Dermal Residue = inner dosimeter residues + head/neck residues + glove residues

c Total Potential Dermal Exposure (μg/lb ai handled) = Total Dermal Residue (μg) /lb ai handled

Table 9. Total Dermal Exposure (Including Hands, Face/Neck) for Trial D (µg/lb ai handled)

Replicate[a]	Major Position	Total Inner Dermal Dosimeter (ug/sample)[b]	Head/Neck Pads (ug/sample)	Total Dosimeter Gloves (ug/sample)	Total Potential Dermal Residue (ug/sample)[c]	lbs ai handled	Total Potential Dermal Exposure (ug/lb ai handled)[d]
38	Line Tender	233	247	174	654	9.82	67.0
39	Spray Man	438	2,520	3,020	5,980	9.82	609
40	Spray Man	476	18,500	438	19,400	5.68	3,410
42	Pot Man	39.0	197	16.0	253	15.5	16.0
43	Pot Man	196	562	43.0	801	15.5	52.0
44	Line Tender	60.0	2,850	56.0	2,960	10.2	292
45	Pot Man	113	627	76.0	816	18.5	44.0
46	Pot Man	66.0	289	49.0	404	18.5	22.0
47	Pot Man	88.0	962	39.0	1,090	18.5	59.0
48	Spray Man	1,600	3,610	1,670	6,880	10.2	678
49	Spray Man	775	18,300	1,610	20,700	8.32	2,490
50	Line Tender	2,150	174	157	2,480	8.32	298
Overall Average							**670**
Overall Geomean							177
Overall Standard Deviation							1,110
CV (%)							**165**

a The final report does not include data for replicates 41 and 51. It is unclear why this is the case; the analytical report shows that dermal and inhalation samples for these two replicates were analyzed.

b Inner dosimeter values represent dermal exposure while wearing personal protective equipment (PPE) as all workers wore a Tyvek coverall over their work clothes.

c Total Potential Dermal Residue = inner dosimeter residues + head/neck residues + glove residues

d Total Potential Dermal Exposure (µg/lb ai handled) = Total Dermal Residue (µg) /lb ai handled

Table 10. Summary of Total Potential Dermal Exposures (Including Hands, Face/Neck) For Each Job Category and Trial (µg/lb ai handled)

Stats	Trial A			Trial B			Trial C			Trial D		
	PM	SM	LT	PM	SM	LT	PM	SM	LT	PM	SM	LT
Average	816	2,150	2,530	152	6,910	3,960	252	2,920	424	39.0	1,800	219
Geomean	702	1,680	2,300	150	6,060	1,230	251	2,510	414	34.0	1,370	180
Standard Deviation	556	1,690	1,270	33.0	3,430	7,650	37.0	2,110	131	19.0	1,380	132
CV (%)	68.0	78.0	50.0	21.0	50.0	193	15.0	72.0	31.0	48.0	77.0	60.0

PM = Pot Man; SM = Spray Man; LT = Line Tender

Table 11. Hand Exposures For Trial A (μg/lb ai handled) Based on Dosimeter Gloves

Sample Number	Major Position	Hand Residue (μg)	lbs ai handled	Hand Exposure (μg/lb ai handled)[a]
1 - glove a	Spray Man	66,500	39.2	1,700
2 - glove a	Line Tender	11,100	9.50	1,170
3 - glove a	Line Tender	10,100	24.4	413
4 - glove a	Line Tender	4,880	9.50	514
5 - glove a	Pot Man	15,400	38.0	405
6 - glove a	Spray Man	13,600	38.0	359
7 - glove a	Pot Man	67,000	39.2	1,710
8 - glove a	Pot Man	20,800	39.2	530
9 - glove a	Spray Man	8,870	20.3	437
10 - glove a	Spray Man	29,700	12.7	2,340
11 - glove a	Pot Man	7,230	40.6	178
12 - glove a	Line Tender	29,800	20.3	1,470
13 - glove a	Spray Man	19,000	29.2	651
14 - glove a	Pot Man	16,000	29.2	547
15 - glove a	Spray Man	14,500	7.50	1,930
16 - glove a	Line Tender	88,000	20.3	4,330
Overall Average				1,170
Overall Geomean				**823**
Overall Standard Deviation				**1,080**
CV (%)				**92.0**

Note: Glove samples #1, 2, 3, 4, 5, 6, 7 and 16 were extracted on 11/30 and found to be too concentrated. Further dilutions were made on 12/1 and rerun on the same day.

a Hand Exposure (μg/lb ai handled) = Hand residue (μg) /lb ai handled

Table 12. Hand Exposures For Trial B (µg/lb ai handled) Based on Dosimeter Gloves

Sample Number	Major Position	Hand Residue (µg)	lbs ai handled	Hand Exposure (µg/lb ai handled)[a]
17 - glove a	Line Tender	252	8.95	28.0
18 - glove a	Spray Man	1,440	6.97	206
19 - glove a	Spray Man	569	10.9	52.0
20 - glove a	Line Tender	1,070	8.95	120
21 - glove a	Pot Man	42.0	17.9	2.00
22 - glove a	Spray Man	525	9.83	53.0
23 - glove a	Pot Man	2.00	17.2	0.120
24 - glove a	Line Tender	183	8.60	21.0
25 - glove a	Line Tender	172	8.60	20.0
26 - glove a	Spray Man	1,440	7.38	195
27 - glove a	Spray Man	511	6.85	75.0
28 - glove a	Line Tender	74.0	5.97	12.0
29 - glove a	Line Tender	112	5.97	19.0
30 - glove a	Pot Man	8.00	11.9	1.00
31 - glove a	Spray Man	617	5.10	121
Overall Average				**62.0**
Overall Geomean				**21.0**
Overall Standard Deviation				**68.0**
CV (%)				111

a Hand Exposure (µg/lb ai handled) = Hand residue (µg) / lb ai handled

Table 13. Hand Exposures For Trial C (μg/lb ai handled) Based on Dosimeter Gloves

Sample Number	Major Position	Hand Residue (μg)	lbs ai handled	Hand Exposure (μg/lb ai handled)[a]
32 - glove a	Pot Man	115	9.82	12.0
33 - glove a	Line Tender	17.0	9.82	2.00
34 - glove a	Spray Man	370	9.82	38.0
35 - glove a	Spray Man	86.0	10.6	8.00
36 - glove a	Pot Man	6.00	10.6	0.600
37 - glove a	Line Tender	277	10.6	26.0
Overall Average				14.0
Overall Geomean				7.00
Overall Standard Deviation				15.0
CV (%)				102

a Hand Exposure (μg/lb ai handled) = Hand residue (μg) / lb ai handled

Table 14. Hand Exposures For Trial D (µg/lb ai handled) Based on Dosimeter Gloves

Sample Number	Major Position	Hand Residue (µg)	lbs ai handled	Hand Exposure (µg/lb ai handled)[a]
38 - glove a	Line Tender	174	9.82	18.0
39 - glove a	Spray Man	803	9.82	82.0
39 - glove b		2,210	9.82	225
40 - glove a	Spray Man	438	5.68	77.0
42 - glove a	Pot Man	16.0	15.5	1.10
43 - glove a	Pot Man	43.0	15.5	3.00
44 - glove a	Line Tender	56.0	10.2	6.00
45 - glove a	Pot Man	76.0	18.5	4.00
46 - glove a	Pot Man	49.0	18.5	3.00
47 - glove a	Pot Man	39.0	18.5	2.00
48 - glove a	Spray Man	1,670	10.2	164
49 - glove a	Spray Man	1,610	8.32	194
50 - glove a	Line Tender	157	8.32	19.0
Overall Average				**61.0**
Overall Geomean				**16.0**
Overall Standard Deviation				**82.0**
CV (%)				**133**

a Hand Exposure (µg/lb ai handled) = Hand residue (µg) / lb ai handled

Table 15. Summary of Hand Exposures Based on Dosimeter Gloves For Each Job Category and Trial (µg/lb ai handled)

Stats	Trial A			Trial B			Trial C			Trial D		
	PM	SM	LT	PM	SM	LT	PM	SM	LT	PM	SM	LT
Average	674	1,240	1,580	1.00	117	36.7	6.20	22.9	14.0	2.50	186	14.0
Geomean	514	960	1,100	0.600	100.0	26.3	2.60	17.5	6.80	2.30	166	12.3
Standard Deviation	598	856	1,600	1.20	69.4	40.9	7.90	20.9	17.3	1.10	95.1	7.40
CV (%)	88.7	69.3	102	113	59.3	112	128	91.4	124	43.5	51.2	52.6

PM = Pot Man; SM = Spray Man; LT = Line Tender

Table 16. Head/Neck Exposures For Trail A (µg/lb ai handled) Based on Head/Neck Pads

Sample Number	Major Position	Residues (µg)	Residues Adjusted for Head/Neck Areas (µg)[a]	Total head/neck residues (µg)	lbs ai handled	Head/Neck Exposure (µg/lb ai handled)
1 - chest pad	Spray Man	310	1,880	2,570	39.2	66.0
1 - back pad		91.3	694			
2 - chest pad	Line Tender	2,170	13,100	13,600	9.50	1,430
2 - back pad		62.6	476			
3 - chest pad	Line Tender	2,300	13,900	14,500	24.4	593
3 - back pad		73.2	556			
4 - chest pad	Line Tender	1,190	7,220	7,280	9.50	767
4 - back pad		8.60	65.4			
5 - chest pad	Pot Man	295	1,780	1,910	38.0	50.0
5 - back pad		16.7	127			
6 - chest pad	Spray Man	489	2,960	2,980	38.0	78.0
6 - back pad		2.70	20.5			
7 - chest pad	Pot Man	262	1,590	1,600	39.2	41.0
7 - back pad		2.50	19.0			
8 - chest pad	Pot Man	827	5,000	5,080	39.2	130
8 - back pad		10.7	81.3			
9 - chest pad	Spray Man	1,930	11,700	11,800	20.3	580
9 - back pad		11.4	86.6			
10 - chest pad	Spray Man	710	4,300	4,360	12.7	343
10 - back pad		8.10	61.6			
11 - chest pad	Pot Man	453	2,740	3,050	40.6	75.0
11 - back pad		40.6	309			
12 - chest pad	Line Tender	1,710	10,400	10,500	20.3	518
12 - back pad		19.4	147			
13 - chest pad	Spray Man	225	1,360	1,390	29.2	48.0
13 - back pad		3.80	28.9			
14 - chest pad	Pot Man	191	1,160	1,320	29.2	45.0
14 - back pad		22.0	167			
15 - chest pad	Spray Man	2,700	16,300	16,500	7.50	2,190
15 - back pad		16.2	123			
16 - chest pad	Line Tender	136	820	922	20.3	45.0
16 - back pad		13.5	103			
Overall Average						**438**
Overall Geomean						**182**
Overall Standard Deviation						**606**
CV (%)						**138**

a Values used to calculate the areas of the head/neck are as follows: Head/Neck Pad = 100 cm^2, Head = 1300 cm^2, Face = 650 cm^2, Back of the neck = 110 cm^2, Front of the neck = 150 cm^2

b Head/Neck Exposure (µg/lb ai handled) = Head/neck residue (µg) /lb ai handled

Table 17. Head/Neck Exposures For Trail B (µg/lb ai handled) Based on Head/Neck Pads

Sample Number	Major Position	Residues (µg)	Residues Adjusted for Head/Neck Areas (µg)[a]	Total head/neck residues (µg)	lbs ai handled	Head/Neck Exposure (µg/lb ai handled)
17 - chest pad	Line Tender	182	1,100	1,110	8.95	124
17 - back pad		1.15	8.70			
18 - chest pad	Spray Man	12,500	75,300	75,400	6.97	10,800
18 - back pad		3.79	28.8			
19 - chest pad	Spray Man	9,070	54,900	55,800	10.9	5,120
19 - back pad		115	871			
20 - chest pad	Line Tender	338	2,050	2,060	8.95	230
20 - back pad		1.41	10.7			
21 - chest pad	Pot Man	78.8	477	481	17.9	27.0
21 - back pad		0.580	4.40			
22 - chest pad	Spray Man	7,210	43,600	43,700	9.83	4,450
22 - back pad		13.1	99.8			
23 - chest pad	Pot Man	43.7	264	270	17.2	16.0
23 - back pad		0.760	5.80			
24 - chest pad	Line Tender	108	652	662	8.60	77.0
24 - back pad		1.32	10.00			
25 - chest pad	Line Tender	27,200	165,000	165,000	8.60	19,100
25 - back pad		6.91	52.5			
26 - chest pad	Spray Man	6,970	42,200	42,400	7.38	5,750
26 - back pad		31.8	242			
27 - chest pad	Spray Man	6,940	42,000	42,100	6.85	6,140
27 - back pad		10.7	81.4			
28 - chest pad	Line Tender	40.2	244	252	5.97	42.0
28 - back pad		1.18	9.00			
29 - chest pad	Line Tender	1,130	6,830	6,940	5.97	1,160
29 - back pad		14.1	107			
30 - chest pad	Pot Man	33.1	200	226	11.9	19.0
30 - back pad		3.42	26.0			
31 - chest pad	Spray Man	742	4,490	4,820	5.10	945
31 - back pad		44.0	335			
Overall Average						**3,600**
Overall Geomean						**552**
Overall Standard Deviation						**5,400**
CV (%)						**150**

a Values used to calculate the areas of the head/neck are as follows: Head/Neck Pad = 100 cm^2, Head = 1300 cm^2, Face = 650 cm^2, Back of the neck = 110 cm^2, Front of the neck = 150 cm^2

b Head/Neck Exposure (µg/lb ai handled) = Head/neck residue (µg) /lb ai handled

Table 18. Head/Neck Exposures For Trail C (µg/lb ai handled) Based on Head/Neck Pads

Sample Number	Major Position	Residues (µg)	Residues Adjusted for Head/Neck Areas (µg)[a]	Total head/neck residues (µg)	lbs ai handled	Head/Neck Exposure (µg/lb ai handled)
32 - chest pad	Pot Man	179	1,080	1,090	9.82	111
32 - back pad		0.890	6.80			
33 - chest pad	Line Tender	381	2,310	2,310	9.82	235
33 - back pad		0.770	5.90			
34 - chest pad	Spray Man	6,820	41,300	41,300	9.82	4,210
34 - back pad		8.53	64.8			
35 - chest pad	Spray Man	2,050	12,400	12,400	10.6	1,170
35 - back pad		3.41	25.9			
36 - chest pad	Pot Man	134	810	845	10.6	80.0
36 - back pad		4.59	34.9			
37 - chest pad	Line Tender	359	2,170	2,190	10.6	207
37 - back pad		3.18	24.2			
Overall Average						1,000
Overall Geomean						359
Overall Standard Deviation						1,620
CV (%)						162

a Values used to calculate the areas of the head/neck are as follows: Head/Neck Pad = 100 cm^2, Head = 1300 cm^2, Face = 650 cm^2, Back of the neck = 110 cm^2, Front of the neck = 150 cm^2

b Head/Neck Exposure (µg/lb ai handled) = Head/neck residue (µg) /lb ai handled

Table 19. Head/Neck Exposures For Trail D (µg/lb ai handled) Based on Head/Neck Pads

Sample Number	Major Position	Residues (µg)	Residues Adjusted for Head/Neck Areas (µg)[a]	Total head/neck residues (µg)	lbs ai handled	Head/Neck Exposure (µg/lb ai handled)
38 - chest pad	Line Tender	40.5	245	247	9.82	25.0
38 - back pad		0.300	2.30			
39 - chest pad	Spray Man	416	2,520	2,520	9.82	257
39 - back pad		0.960	7.30			
40 - chest pad	Spray Man	2,980	18,000	18,500	5.68	3,250
40 - back pad		56.6	430			
42 - chest pad	Pot Man	32.2	195	197	15.5	13.0
42 - back pad		0.280	2.10			
43 - chest pad	Pot Man	90.5	548	562	15.5	36.0
43 - back pad		1.89	14.4			
44 - chest pad	Line Tender	469	2,840	2,850	10.2	281
44 - back pad		1.18	9.00			
45 - chest pad	Pot Man	100.0	606	628	18.5	34.0
45 - back pad		2.80	21.3			
46 - chest pad	Pot Man	46.1	279	289	18.5	16.0
46 - back pad		1.32	10.00			
47 - chest pad	Pot Man	156	946	962	18.5	52.0
47 - back pad		2.11	16.0			
48 - chest pad	Spray Man	582	3,520	3,610	10.2	355
48 - back pad		11.3	86.3			
49 - chest pad	Spray Man	3,030	18,300	18,300	8.32	2,200
49 - back pad		1.00	7.60			
50 - chest pad	Line Tender	25.9	157	174	8.32	21.0
50 - back pad		2.35	17.9			
Overall Average						**545**
Overall Geomean						**102**
Overall Standard Deviation						**1,050**
CV (%)						**193**

a Values used to calculate the areas of the head/neck are as follows: Head/Neck Pad = 100 cm^2, Head = 1300 cm^2. Face = 650 cm^2, Back of the neck = 110 cm^2, Front of the neck = 150 cm^2

b Head/Neck Exposure (µg/lb ai handled) = Head/neck residue (µg) /lb ai handled

Table 20. Summary of Head/Neck Exposures Based on Head/Neck Pads For Each Job Category and Trial (µg/lb ai handled)

Stats	Trial A			Trial B			Trial C			Trial D		
	PM	SM	LT	PM	SM	LT	PM	SM	LT	PM	SM	LT
Average	68.3	223	671	20.5	5,540	3,460	95.5	2,690	221	30.1	1,520	109
Geomean	61.9	137	434	20.0	4,490	357	94.3	2,220	221	26.4	899	52.9
Standard Deviation	36.8	234	503	5.70	3,180	7,700	22.1	2,150	20.2	16.2	1,460	149
CV (%)	53.9	105	74.9	28.0	57.5	222	23.1	79.8	9.10	53.7	96.4	136

PM = Pot Man; SM = Spray Man; LT = Line Tender

Table 21. Potential Inhalation Exposure For Trial A (µg/lb ai handled) Based on Residue Levels Found in Air Sampling Filters

Sample Number	Major Position	Residue (µg)	Duration (min)	Flow rate (L/min.)	Concen. (µg/m^3)[a]	lbs ai handled	Vent. Rate L/min (m^3/min)[b]	Inhalation exposure (ug/lb ai handled)[c]
1 - filter	Spray Man	19.0	375	1.47	34.5	39.2	0.0167	5.50
2 - filter	Line Tender	70.8	412	1.51	114	9.50	0.0167	82.7
3 - filter	Line Tender	256	390	1.51	434	24.4	0.0167	116
4 - filter	Line Tender	26.5	385	1.50	46.0	9.50	0.0167	31.1
5 - filter	Pot Man	9.92	360	1.51	18.3	38.0	0.0167	2.90
6 - filter	Spray Man	52.6	360	1.50	97.2	38.0	0.0167	15.4
7 - filter	Pot Man	7.40	350	1.53	13.9	39.2	0.0167	2.10
8 - filter	Pot Man	10.2	365	1.52	18.4	39.2	0.0167	2.90
9 - filter	Spray Man	35.4	271	1.51	86.9	20.3	0.0167	19.4
10 - filter	Spray Man	8.97	271	1.49	22.2	12.7	0.0167	7.90
11 - filter	Pot Man	9.72	281	1.50	23.1	40.6	0.0167	2.70
12 - filter	Line Tender	21.4	262	1.52	53.6	20.3	0.0167	11.6
13 - filter	Spray Man	35.0	262	1.43	93.4	29.2	0.0167	14.0
14 - filter	Pot Man	7.51	267	1.52	18.6	29.2	0.0167	2.80
15 - filter	Spray Man	46.6	254	1.53	120	7.50	0.0167	67.8
16 - filter	Line Tender	9.72	265	1.51	24.3	20.3	0.0167	5.30
Overall Average								**24.4**
Overall Geomean								10.7
Overall Standard Deviation								34.1
CV (%)								140

a Concentration (µg/m^3) = [(Residue (µg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b Recommended inhalation rate for light activities.

c Exposure (µg/lb ai handled) = [(Concentration (µg/m^3) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

Table 22. Potential Inhalation Exposure For Trial B (µg/lb ai handled) Based on Residue Levels Found in Air Sampling Filters

Sample Number	Major Position	Residue (µg)	Duration (min)	Flow rate (L/min.)	Concen. (µg/m^3)[a]	lbs ai handled	Vent. Rate L/min (m^3/min)[b]	Inhalation exposure (ug/lb ai handled)[c]
17 - filter	Line Tender	36.2	101	1.50	240	8.95	0.0167	45.1
18 - filter	Spray Man	786	101	1.50	5,190	6.97	0.0167	1,260
19 - filter	Spray Man	877	101	1.51	5,760	10.9	0.0167	892
20 - filter	Line Tender	86.3	101	1.50	571	8.95	0.0167	108
21 - filter	Pot Man	15.9	101	1.50	105	17.9	0.0167	9.90
22 - filter	Spray Man	647	67.0	1.50	6,420	9.83	0.0167	731
23 - filter	Pot Man	14.0	67.0	1.48	141	17.2	0.0167	9.20
24 - filter	Line Tender	17.5	67.0	1.49	176	8.60	0.0167	22.9
25 - filter	Line Tender	336	67.0	1.50	3,350	8.60	0.0167	436
26 - filter	Spray Man	701	67.0	1.50	6,970	7.38	0.0167	1,060
27 - filter	Spray Man	592	63.0	1.51	6,240	6.85	0.0167	958
28 - filter	Line Tender	9.86	63.0	1.50	104	5.97	0.0167	18.4
29 - filter	Line Tender	67.8	63.0	1.50	716	5.97	0.0167	126
30 - filter	Pot Man	8.86	63.0	1.49	94.4	11.9	0.0167	8.30
31 - filter	Spray Man	43.0	63.0	1.50	454	5.10	0.0167	93.7
Overall Average								**385**
Overall Geomean								**113**
Overall Standard Deviation								**459**
CV (%)								**119**

a Concentration (µg/m^3) = [(Residue (µg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b NAFTA recommended inhalation rate for light activities.

c Exposure (µg/lb ai handled) = [(Concentration (µg/m^3) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

Table 23. Potential Inhalation Exposure For Trial C (µg/lb ai handled) Based on Residue Levels Found in Air Sampling Filters

Sample Number	Major Position	Residue (µg)	Duration (min)	Flow rate (L/min.)	Concen. (µg/m^3)[a]	lbs ai handled	Vent. Rate L/min (m^3/min)[b]	Inhalation exposure (ug/lb ai handled)[c]
32 - filter	Pot Man	3.59	57.0	1.49	42.2	9.82	0.0167	4.10
33 - filter	Line Tender	4.59	57.0	1.50	53.6	9.82	0.0167	5.20
34 - filter	Spray Man	34.5	57.0	1.51	402	9.82	0.0167	38.9
35 - filter	Spray Man	47.7	81.0	1.51	391	10.6	0.0167	50.0
36 - filter	Pot Man	6.82	81.0	1.50	56.2	10.6	0.0167	7.20
37 - filter	Line Tender	7.19	81.0	1.51	58.8	10.6	0.0167	7.50
Overall Average								**18.8**
Overall Geomean								**11.4**
Overall Standard Deviation								**20.2**
CV (%)								**107**

a Concentration (µg/m^3) = [(Residue (µg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b NAFTA recommended inhalation rate for light activities.

c Exposure (µg/lb ai handled) = [(Concentration (µg/m^3) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

Table 24. Potential Inhalation Exposure For Trial D (µg/lb ai handled) Based on Residue Levels Found in Air Sampling Filters

Sample Number	Major Position	Residue (µg)	Duration (min)	Flow rate (L/min.)	Concen. (µg/m^3)[a]	lbs ai handled	Vent. Rate L/min (m^3/min)[b]	Inhalation exposure (ug/lb ai handled)[c]
38 - filter	Line Tender	0.350	211	1.51	1.10	9.82	0.0167	0.400
39 - filter	Spray Man	25.8	203	1.51	84.1	9.82	0.0167	29.0
40 - filter	Spray Man	6.04	184	1.51	21.7	5.68	0.0167	11.8
42 - filter	Pot Man	0.260	151	1.51	1.10	15.5	0.0167	0.200
43 - filter	Pot Man	0.170	163	1.50	0.700	15.5	0.0167	0.100
44 - filter	Line Tender	2.86	190	1.49	10.1	10.2	0.0167	3.10
45 - filter	Pot Man	0.250	210	1.51	0.800	18.5	0.0167	0.100
46 - filter	Pot Man	0.460	214	1.52	1.40	18.5	0.0167	0.300
47 - filter	Pot Man	0.510	199	1.50	1.70	18.5	0.0167	0.300
48 - filter	Spray Man	26.4	182	1.52	95.5	10.2	0.0167	28.6
49 - filter	Spray Man	17.3	157	1.52	72.5	8.32	0.0167	22.8
50 - filter	Line Tender	0.410	92.0	1.50	3.00	8.32	0.0167	0.500
Overall Average								**8.10**
Overall Geomean								**1.40**
Overall Standard Deviation								**11.8**
CV (%)								**146**

a Concentration (µg/m^3) = [(Residue (µg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b NAFTA recommended inhalation rate for light activities.

c Exposure (µg/lb ai handled) = [(Concentration (µg/m^3) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

Table 25. Summary of Inhalation Exposure Based on Air Sampling Filters For Each Job Category and Trial (µg/lb ai handled)

Stats	Trial A			Trial B			Trial C			Trial D		
	PM	SM	LT	PM	SM	LT	PM	SM	LT	PM	SM	LT
Average	2.70	21.7	49.3	9.10	831	126	5.60	44.5	6.30	0.200	23.1	1.40
Geomean	2.60	15.2	28.3	9.10	653	69.5	5.40	44.1	6.20	0.200	21.7	0.900
Standard Deviation	0.300	23.2	48.1	0.800	401	158	2.20	7.80	1.60	0.100	8.00	1.50
CV (%)	13.0	107	97.5	8.40	48.3	126	38.8	17.6	25.7	38.5	34.9	114

PM = Pot Man; SM = Spray Man; LT = Line Tender

Name:
Evaluator

Date

Name:
Peer Reviewer

Date

Name:
Head,

Date

APPENDIX A

Compliance Checklist for "Assessment of Potential Inhalation and Dermal Exposure to Zinc Pyrithione During Outdoor Painting of Ship Hulls With Commercial Antifouling Paint Containing ZINC OMADINE®"

Compliance Checklist

Compliance with OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: Guidelines, 875.1100 (dermal exposure - outdoor), 875.1300 (inhalation exposure - outdoor), and 875.1600 (application exposure monitoring data reporting) is critical. The itemized checklist below describes compliance with the major technical aspects of OPPTS 875.1100, 875.1300 and 875.1600.

Guideline 875.1100

1. *Investigators should submit protocols for review purposes prior to the inception of the study.* This criterion was met.

2. Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts. This criterion was met.

3. The test substance should be a typical end use product of the active ingredient. This criterion was met. However, the test substance used was not prepared and analyzed in the laboratory prior to application, rather, cans of commercial antifoulant paint on-hand at the test site at the time of the trial was used.

4. 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 may be more appropriate in certain cases. This criterion was met.

5. Selected sites and indoor conditions of monitoring should be appropriate to the activity. This criterion was met.

6. A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For outdoorr exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity. This criterion was met.

7. The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate. This criterion was met.

8. Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners. This criterion was met.

9. Any protective clothing worn by the test subjects should be identified and should be consistent with the product label. This criterion was mostly met. For Trial A, the test subjects wore work gloves, rather than chemical-resistant gloves while they worked. These gloves were made of heavy cotton knit with rubberized palms that appeared to be somewhat absorbent, according to the study author. As a result, subjects in this trial experienced the greatest hand exposures. The label for the different paint products state different levels of hand protection: Intersmooth 460 Blue states that "gloves" should be worn, Intersmooth 460 Brown states that "rubber gloves" are to be worn, and Intersmooth 460 Red and Micron 66 Black state that "chemical resistant gloves" are to be worn.

10. The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities. This criterion was met.

11. Dermal exposure pads used for estimating dermal exposure to sprays should be constructed from paper-making pulp or similar material (i.e., alpha-cellulose), approximately 1 mm thick, that will absorb a considerable amount of spray without disintegrating. The alpha-cellulose material should not typically require pre-extraction to remove substances that interfere with residue analysis. This should be determined prior to using the pads in exposure tests. This criterion was met with the use of whole body dosimeters and head/neck pads.

12. Dermal exposure pads used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulation should be constructed from layers of surgical gauze. The pad should be bound so that an area of gauze at least 2.5 inch square is left exposed. The gauze must be checked for material that would interfere with analysis and be pre-extracted if necessary. This criterion is not applicable to this study. The formulated test substance was antifoulant paint.

13. A complete set of pads for each exposure period should consist of 10 to 12 pads. If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the worker's outer garments. Pads should be attached under both upper and lower outer garments, particularly in regions expected to receive maximum exposure. Pads under clothing should be near, but not covered by, pads on the outside of the clothing. This criterion was met with the use of whole body dosimeters and head/neck pads.

14. If exposed pads are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination. This criterion does not apply to this study.

15. Hand rinses should be performed during preliminary studies to ensure that interferences are not present. Plastic bags designed to contain 0.5 gal and strong enough to withstand vigorous shaking (i.e., at least 1 mil inch thickness) should be used. During preliminary studies, plastic bags must be shaken with the solvent to be used in the study to ensure that material which may interfere with analysis is not present. This criterion does not apply to this study. Dosimeter gloves were used rather than hand washes.

16. The analytical procedure must be capable of quantitative detection of residues on exposure pads at a level of 1 ug/cm2 (or less, if the dermal toxicity of the material under study warrants greater sensitivity). This criterion was met.

17. The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study. These criteria were partially met. For laboratory fortifications, only 1 to 4 replicates were run for each fortification level per matrix, which varied among each trial. For field fortifications, only 3 replicates were run for each fortification level per matrix.

18. If the stability of the material of interest is unknown, or if the material is subject to degradation, the investigator must undertake and document a study to ascertain loss of residues while the pads are worn. It is recommended that collection devices be fortified with the same levels expected to occur during the field studies. The dosimeters should be exposed to similar conditions and for the same time period as those expected during field studies. This criterion was met.

19. Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent. This criterion was met. However, it should be noted that the study author corrected for all field recoveries <100 percent. Versar only corrected for field fortification values <90 percent.

20. Field data should be documented, including chemical information, area description, environmental conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations. This criterion was met.

21. A sample history sheet must be prepared by the laboratory upon receipt of samples. This criterion was met.

Guideline 875.1300

1. When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used. This criterion was met.

2. The analytical procedure must be capable of measuring exposure to 1 ug/hr (or less, if the toxicity of the material under study warrants greater sensitivity). This criterion was met.

3. A trapping efficiency test for the monitoring media chosen must be documented. This criterion was met.

4. Air samples should also be tested for breakthrough to ensure that collected material is not lost from the medium during sampling. It is recommended that at least one test be carried out where the initial trap contains 10X the highest amount of residue expected in the field. This criterion was met.

5. If trapping media or extracts from field samples are to be stored after exposure, a stability test of the compound of interest must be documented. Media must be stored under the same conditions as field samples. Storage stability samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage should be chosen so that the longest corresponds to the longest projected storage period for field samples. This criterion was met.

6. A personal monitoring pump capable of producing an airflow of at least 2 L/min. should be used and its batteries should be capable of sustaining maximum airflow for at least 4 hours without recharging. Airflow should be measured at the beginning and end of the exposure period. This criterion was not met. Personal air sampling pumps were set to produce an airflow of 1.5 L/min.

7. Appropriate air sampling media should be selected. The medium should entrap a high percentage of the chemical passing through it, and it should allow the elution of a high percentage of the entrapped chemical for analysis. This criterion was met. Satisfactory fortified sample recoveries indicate the appropriate sampling media was selected.

8. If exposed media are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination. This criterion was not met. Air sampling filters were capped and stored frozen in individually in a fresh, locking polyethylene storage bags prior to extraction.

9. Personal monitors should be arranged with the intake tube positioned downward, as near as possible to the nose level of the subject. This criterion was met.

10. Field calibration of personal monitors should be performed at the beginning and end of the exposure period. This criterion was met.

11. Field fortification samples and blanks should be analyzed for correction of residue losses occurring during the exposure period. Fortified samples and blanks should be fortified at the expected residue level of the actual field samples. Fortified blanks should be exposed to the same weather conditions. This criterion was met.

12. Respirator pads should be removed using clean tweezers and placed in protective white crepe filter paper envelopes inside sandwich bags. The pads should be stored in a chest containing ice until they are returned to the laboratory, where they should be stored in a freezer prior to extraction. This criterion does not apply to this study, as respirators were not worn by test subjects.

13. Analysis methods should be documented and appropriate. This criterion was met.

Guideline 875.1600

1. A title page and table of contents should be included that conform with existing Agency requirements. The table of contents should indicate the overall organization of the report and lists the page numbers for each section. Tables, figures, and appendices should be listed separately. This criterion was met.

2. The introduction and summary should contain the purpose of the study and what requirements the study is intended to satisfy. These sections should cover at a minimum the following points: the chemical and formulation; the application rate in units of active ingredient per unit of area, volume of spray per unit of area, and total units of active ingredient handled; the number of individuals participating in the study, indicating duties and clothing worn during monitored activity; any unusual problems resulting in deviations from the protocol; and a name and phone number of a contact person for the study. This criterion was met.

3. The materials and methods section should be in a narrative format and contain all details with regard to the materials, equipment, experimental design, site description, and procedures used in conducting the study. This criterion was met.

4. The analytical methods used in the study for each test (i.e. efficiency of extraction, field fortification) are to be described fully and include method validation data, recovery and method sensitivity data, stability date, sample chromatograms, and sample calculations. Preparation and handling of the samples throughout the method should be described in detail. Additionally, instrumentation, equipment, reagents, and operating conditions should be fully described. These criteria were met.

5. The results section should contain the scientific results of the study and must be interpretive. Narrative and tables describing all calculations should be presented. The results shall be reported as described in OPPTS 875.1000 under paragraphs (h)(6) and (i)(6). A sample calculation for each separate mathematical manipulation must be provided. These criteria were met.

6. The name, signature and date of the person(s) responsible for the major quality control duties should be included. Also included should be the procedures undertaken by the registrant/laboratory to validate the report. This may be a list of all audits and reviews performed that includes the study activity, the date activities were performed, and the individual(s) involved. Any deficiencies and subsequent corrective action should be described. These criteria were met.

7. The name and address of the location of the raw data and final report should be reported. This criterion was met.

8. A signature page containing the dated signatures of all professionals and scientists involved with the study should be included. This criterion was met.

9. Tables, figures, and references must be presented in a standard and consistent format. Tables are to be numbered using Arabic numerals rather than Roman numerals. This criterion was met.

10. The Appendix(es) should contain copies of all relevant communications, a copy of the Agency-approved protocol, and sample chromatograms, diagrams, photographs, or other pictoral material. This criterion was met.

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 5, 2008

MEMORANDUM

SUBJECT: Ethics Review of Zinc Pyrithione Worker Exposure Study

TO: Timothy Leighton
Antimicrobial Division

FROM: Kelly Sherman
Human Research Ethics Reviewer
Office of Pesticide Programs

REF: Wu, M. (2005) Assessment of Potential Inhalation and Dermal Exposure to Zinc Pyrithione During Outdoor Painting of Ship Hulls with Commercial Antifouling Paint Containing ZINC OMADINE®. Unpublished study prepared by Arch Chemicals Inc. under Study Identification No. BWE03001. 630 p. (MRID 46707001)

I have reviewed the referenced document and determined that all applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied.

Summary Characteristics of the Research

In this research, 31 dry dock workers were monitored as they performed tasks associated with the commercial application of antifouling paint to the hulls of commercial cargo and passenger ships. The research was conducted between November 2004 and April 2005 in Boston, Massachusetts and Freeport, Grand Bahama Island. Subjects wore whole-body dosimeters under fresh work clothes and Tyvek® hooded coveralls, dosimeter gloves under work gloves, dosimeter patches on the back of their work shirts and on the front of their coveralls, and personal air sampling pumps for monitoring dermal and inhalation exposure.

Attachment (2)

Some of the 31 workers were monitored more than once, for a total of 49 "replicates." All of the subjects were professional dry dock workers who normally performed tasks associated with the commercial application of antifouling paint to ship hulls. No information is provided about how the subjects were recruited, or what they were told of the purposes, procedures, risks, benefits, costs, and other aspects of the research. The report does not indicate whether the subjects consented to participate, or what form their consent took. The research was not reported to have been overseen by an IRB or any comparable independent ethics review entity.

1. **Value of the Research to Society**: The purpose of this study was to monitor and quantify the exposure levels of zinc pyrithione to dry dock workers as they perform tasks associated with applying antifouling paint to the hulls of commercial cargo or passenger ships. The study was funded by Arch Chemicals Inc. It contributes to the assessment of worker exposure while mixing, loading, and applying zinc pyrithione and possibly other types of antifouling paint to commercial cargo and passenger ships.

2. **Subject Selection**: Although participating shipyards were reportedly selected to represent a typical range of circumstances and practices, no information is given about how the subjects were recruited or selected. Their gender, age, and pregnancy or nursing status is not reported. There is no indication that any subjects came from an especially vulnerable group.

3. **Risk-Benefit Ratio**: Neither risks to the subjects nor actions taken to minimize those risks are discussed. Since subjects were performing their usual jobs and wearing both PPE and whole-body dosimeters, the risks associated with their participation in the research were low. The report does not identify societal benefits of the research or how they would be distributed, or how the investigators weighed likely benefits of the research against the risks to individual subjects.

4. **Independent Ethics Review**: The study does not report any independent ethics oversight or review of the protocol or of the conduct of the research.

5. **Informed Consent**: The report is silent about whether informed consent was obtained from the subjects. Because subjects wore extensive dosimetry, it is implausible that their participation was not consensual. What is less clear is whether it was adequately informed.

6. **Respect for Potential and Enrolled Subjects**: The report does not contain identifying information about any of the subjects. It is not reported whether subjects were free to withdraw from the research.

Applicable Standards

This research was initiated in December 2003, well before April 7, 2006, the effective date of EPA's amended Rule for the Protection of Human Subjects of Research. The report was submitted to EPA on December 5, 2005, before the effective date of EPA's Amended Rule, and thus it was not subject to the requirement of 40 CFR §26.1303 to document the ethical conduct of the research.

The amount of active ingredient handled was not manipulated by the investigators, nor was subject behavior or the equipment they used influenced by the investigators. Therefore, the research may not constitute "research involving intentional exposure of a human subject" as that phrase is defined in the rule at 40 CFR §26.1102(i). However, documentation of how cooperating employees and employers were recruited is inadequate to support a definitive finding.

The Agency's rule defines standards that EPA must apply in deciding whether to rely on research—like this study—which may have involved intentional exposure of human subjects. (See 40 CFR §26 subpart Q.) Because this study was initiated before the effective date of the rule, the applicable acceptance standards from 40 CFR §26 are these:

> **§26.1703. Prohibition of reliance on research involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children.** Except as provided in §26.1706, in actions within the scope of §26.1701 EPA shall not rely on data from any research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.
>
> **§26.1704. Prohibition of reliance on unethical human research with nonpregnant adults conducted before April 7, 2006.** Except as provided in §26.1706, in actions within the scope of §26.1701, EPA shall not rely on data from any research initiated before April 7, 2006, if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (*e.g.*, the research was intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the research was conducted. This prohibition is in addition to the prohibition in §26.1703.

FIFRA §12(a)(2)(P) also applied to this research. This provision reads:

> In general, [i]t shall be unlawful for any person . . . to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.

Compliance with Applicable Standards

All subjects were adults. The study is silent with respect to the age, sex, and pregnancy or nursing status of the subjects, but there is no indication that any of the subjects were pregnant or nursing women. In the absence of any information suggesting that pregnant or nursing women were among the subjects, the Agency's view is that reliance on the study is not prohibited by 40 CFR 26.1703.

40 CFR §26.1704 forbids EPA to rely on data from pre-rule research—such as this study—if there is "clear and convincing evidence that the conduct of the research was fundamentally unethical (e.g., the research was intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the research was conducted." This study had a clear research purpose and was not designed with the intent to seriously harm the subjects. There is no direct evidence that the subjects provided consent, but it is unlikely that the workers could have been compelled to wear the dosimeters and air sampling equipment without their consent. Although there are significant gaps in the documentation of the ethical conduct of this research, these gaps do not in themselves amount to "clear and convincing evidence." I found no evidence that this research was fundamentally unethical, or that its conduct was significantly deficient relative to standards prevailing at the time it was conducted. 40 CFR §26.1704 does not prohibit EPA reliance on this research.

FIFRA §12(a)(2)(P) requires that human subjects of research with pesticides be "fully informed of . . . any physical and mental health consequences which are reasonably foreseeable" from their participation in the research. The study does not report what the subjects were told about the potential health effects of participating in this research, or whether they consented to participate. The lack of documentation regarding informed consent is a significant deficiency, but this deficiency does not, in my judgment, necessarily indicate that the subjects were not properly informed or that their participation was non-consensual, in violation of FIFRA §12(a)(2)(P). Uncertainty in this respect could be removed if further information were obtained about the process and content of informed consent in this study.

Conclusion

Although there are many significant gaps in the documentation of the ethical conduct of this study, there is no clear evidence that the research was intended to harm participants, or that it was fundamentally unethical in other ways. Deficient documentation does not itself constitute evidence that the ethical conduct of this study was deficient relative to standards prevailing when it was conducted.

I therefore conclude that, whether or not the reported research met the regulatory definition of "research involving intentional exposure of a human subject," there is no barrier in law or regulation to EPA's relying on this research in its actions taken under FIFRA or §408 of FFDCA. I defer to others for a full review of the scientific validity of this study. If it were determined not to have scientific validity, it would also not be ethically acceptable.