Appendix A

Migration of DINP from Polyvinyl Chloride (PVC) Children's Products

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I. Background

Dialkyl phthalate esters impart flexibility to rigid polyvinyl chloride polymer (PVC). Previous studies by the Inhalation Toxicology Research Institute (ITRI) for the U. S. Consumer Product Safety Commission (CPSC) examined the migration of di 2-ethylhexyl phthalate (DEHP) from teethers and pacifiers (*Phthalate Ester Migration from Polyvinyl Chloride Consumer Products*, R. L. Hanson, ITRI, 1983). These studies, which use an air driven piston to simulate mouthing and chewing, demonstrate that DEHP migrated from the pacifiers and teethers. The purpose of the present study is to identify phthalate containing products that are likely to be mouthed by children and to determine the amount of phthalate migration from these products using *in vitro* and *in vivo* tests.

II. Methods

A. Determination of total phthalates from PVC

1. Total phthalates

Samples consisting of thin plastic sheets were cut into small pieces. Thicker samples were cooled by liquid nitrogen and ground to a powder with a micro mill. A weighed portion of the cut sheet or powdered plastic was placed in a Soxhlet extraction thimble and extracted for six hours with 80 ml of hexane. The hexane was evaporated and the percent by weight of phthalates was calculated from the weight of phthalates recovered and the initial weight of the sample extracted.

2. Identification and quantitation of phthalates

Phthalates obtained from the Soxhlet extraction of PVC products were dissolved in hexane and identified by means of gas chromatography/mass spectrometry (GC/MS) by comparison to spectra of known phthalate esters. Comparisons of known with unknown phthalate esters were made by matching retention times of total ion chromatograms and the selective ion chromatograms at mass 149. The mass 149 ion is specific for phthalate esters. Quantitative analysis of phthalates was performed by HP-6890 GC/MS system as follows:

1. GC conditions
   Column, J & W DB-1, 0.25 mm ID, 30 m, 0.1μm
   Oven Temperature, 100 °C for 3 min, 100 °C to 270 °C at 40 °C/min,
   270 °C for 30 min
   Injector Temperature, 325 °C
   Carrier gas, Helium, 1.0 ml/min
   Injection , 1 μl splitless

2. MS analysis

Butyl benzyl phthalate (BBP) was used as an internal standard since it was found as an impurity in DINP at less than 0.5% of total phthalates. Selective ion mode was used in quantitative analysis. Phthalates were quantified by use of the peak area ratio of unknowns and BBP against the calibration curve of the peak area ratios derived from known concentrations of standard phthalates and BBP. The calibration and analyses of unknowns were performed on the same day.

B. *In vitro* phthalate migration

1. Chemicals and apparatus

The apparatus used for *in vitro* simulation of chewing is shown in Figures 1 and 2. This test apparatus allows up to six specimens to be tested simultaneously. The materials and equipment used are as follows:

Shaking water bath capable of maintaining 37 °C
Six 100 ml stainless steel beakers for holding extraction solution and PVC sample
Air driven pistons, 1.58 cm (5/8 inch) hexagon with an area of 2.18 cm^2 (0.338 in^2)
Air compressor with pressure regulation from 258 mm to 3103 mm Hg (10 to 90 pounds per square inch gauge, PSIG)
Programmable controller to activate the pistons, operated at 4 seconds per cycle (2 seconds of applied air pressure, and two seconds of relaxation)
Separatory funnels
Hexane (95%, Mallinckrodt)
Simulated saliva solution - Dulbecco's phosphate buffered saline containing 0.16 percent mucin (pH ≈7.2, this is consistent with earlier work done at ITRI)

2. Phthalate migration by shaking

A PVC sample of known surface area was placed in a 250 ml glass stoppered Erlenmeyer flask containing 50 ml of the saliva simulant. The flask was placed in a 37 °C water bath and shaken horizontally for 6 hours at a rate of 60 cycles/min with a travel distance of 2.54 cm (1 in).

3. Phthalate migration by impaction

Samples consisting of thin PVC sheets were cut into disks approximately 7 cm in diameter to prevent significant movement in the stainless steel beaker during impaction. Hollow samples were cut and placed over the piston. Large or odd shaped samples were cut to provide a relatively flat surface. Test specimens smaller than 7 cm tended to move about the beaker and were held in place by a metal rod. Samples were tested intact wherever possible. A Chatillon force gauge measured the force applied by the piston before and after every experiment. Test specimen dimensions were measured and recorded for each experiment.

The normal extraction procedure consisted of adding 50 ml of saliva simulant to the stainless steel beaker holding the item under test. The piston was activated and applied pressure for 2 seconds followed by 2 seconds without pressure. Each test lasted 6 hours at 37 °C. The forces investigated were 0.91 kg, 2.7 kg, and 5.4 kg (2 lbs, 6 lbs, and 12 lbs). The piston sizes were 1.27 cm, 1.59 cm, and 2.54 cm (½", **e** " and 1 ").

4. Extraction of phthalates from saliva simulant using hexane

The test specimen was removed from the beaker and rinsed with a minimum amount of deionized water. The combined aqueous solutions were transferred to a 250 ml glass Erlenmeyer flask. The piston and beaker were rinsed with 50 ml of acetonitrile and combined with the aqueous extraction media. Fifty ml of hexane was then added and the entire mixture was vigorously stirred for 8 minutes and transferred to a separatory funnel. After separation of hexane and aqueous phases, the aqueous phase was extracted with an additional 25 ml of hexane. The combined hexane extracts were allowed to evaporate in an 80 ml beaker at room temperature. The residues were dissolved in approximately 1 ml of hexane and a known amount of butyl benzyl phthalate (BBP) was added as internal standard for GC/MS quantitative analysis.

5. Calculation of migration from impacted and non-impacted surfaces

The area of the surface of an item that was likely to be mouthed when used by a child was assumed to be 11 cm^2. Since the impaction procedure exposes both impacted and non-impacted areas to the buffer, the migration of phthalate had to be apportioned between the amounts migrating from the impacted areas (chewed) and non-impacted areas (mouthed but not chewed). The tooth/gum contact (chewed) area was assumed to be the area of the piston, 2.18 cm^2 and the mouthed area was assumed to be 8.82 cm^2. The apportioning of total release between impacted and non-impacted areas was done algebraically. Knowing the total immersed area, piston area (2.18 cm^2), and total phthalate migration, the migration from the impacted area was calculated as the difference between total migration and the migration from the non-impacted area. The calculation, assuming that the migration rate from non-impacted area is same migration rate as determined in the shaking only experiments, resulted in a ratio of 0.0302[1].

C. *In vivo* phthalate migration

The *in vivo* testing used five duck toys that were identical to sample 2.02. These were identified as D1 through D5. Four disks were cut from each duck with a 2.86 cm tubular cutter and identified as D1-1 through D1-4, D2-1 through D2-4, etc. Two disks from each toy were used for human subject testing and the remaining two were used for impaction or other testing. Ten polytetrafluoroethylene disks served as blanks. Prior to testing, all disks were gently washed with warm soapy water, rinsed and allowed to dry at room temperature.

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[1]The phthalate migration rate (μg/cm^2/hr) of 6 samples was determined by use of shaking only. The same 6 samples were subjected to the impaction procedure. The calculated apportionment ratio was 0.0302.

The human subjects consisted of three female and seven male CPSC staff volunteers who were not involved with the phthalate project. Each was provided with a polytetrafluoroethylene disk and a disk from the toy duck. Each volunteer was instructed to gently chew/mouth a polytetrafluoroethylene disk for 15 minutes. The subjects were then instructed to repeat the process for four 15 minute intervals on a the disk cut from the toy duck. The subjects were allowed 5 minutes to rest between the periods of active mouthing of the disks. For each 15 minute chewing period the subjects were instructed to collect all their saliva in labeled bottles. The total volume of saliva (ml) and pH of the saliva in each bottle were recorded. All saliva samples were diluted to 50 ml with deionized water and treated with 50 ml of acetonitrile. Extraction of the phthalates from the saliva with hexane was performed as described above. The protocol for the *in vivo* tests was approved by the CPSC human subjects committee.

III. Results and Discussion

This study was conducted in four phases. The first phase was a series of experiments performed to determine the conditions for measuring phthalate migration from the test products. The second phase characterized phthalate release from the PVC products. The third phase was a survey of various PVC children's products for phthalate release. The fourth phase was a human subjects mouthing/chewing test to compare *in vitro* and *in vivo* migration rates.

A. Determining test conditions

A flat and smooth PVC teether containing diisononyl phthalate (DINP) was used to evaluate the test conditions for determining the migration rates of phthalates from children's teethers, toys, and pacifiers. The sample could also be tested without cutting the edge which might affect the rate of phthalate release.

1. Recovery of DINP by acetonitrile/ hexane extraction

DINP (10, 25, 50 and 100 μg) was dissolved in hexane. The solutions were air dried and 50 ml each of saliva simulant and acetonitrile added. The mixture was vigorously stirred, treated with acetonitrile and extracted with hexane as described earlier. The percent recoveries of DINP were 122, 93, 82, and 103 respectively with an average recovery of 100% ± 17%.

2. Impaction pressure

A comparison of the release rate of DINP versus force applied is shown in Figure 3. Similar results were obtained for either 2.7 kg (6 lbs) or 5.4 kg (12 lbs) of force and both gave substantially higher release rates (approximately 10 μg/hr) than were obtained by either by shaking only (approximately 3 μg/hr) or with an impaction force of 0.91 kg (2 lbs) (approximately 5 μg/hr). An additional experiment was performed on a higher DINP releasing PVC product with similar results. The release rates for this product were 44.67 μg/hr and 37.41 μg/hr respectively for 2.7 kg (6 lbs) and 5.4 kg (12 lbs) of force.

3. Rate of impaction

The impaction controller allows for varying the rate of impaction, however, the total cycle time is always divided into equal periods of impaction and relaxation. A higher absolute release rate (8.75 μg/hr) was obtained with a four second cycle than with either a six or an eight second cycle (2.88 μg/hr and 3.88 μg/hr respectively). The release rates for cycles of six and eight seconds, when extrapolated to the same number of impactions, however, are similar to the migration rate measured for the four second cycle. The four second cycle impaction rate was chosen to provide the greater number of impacts per unit of time.

4. Extraction time

As shown in Figure 4, the initial migration rates were similar at 2, 4 and 8 hrs but fell off at 24 hrs. After being allowed to stand for one week under ambient laboratory conditions, the samples were retested for an additional 8 hours of impaction. The migration rates were generally similar for this additional period with the highest rate being observed for the sample impacted initially for 8 hrs. Based on these data, an impaction time of 6 hrs appeared to be adequate, for samples with low rates of phthalate migration, to ensure sufficient phthalate for reliable detection and quantitation. Saturation of the simulant with phthalates did not appear to be a problem during the first 8 hrs of extraction.

5. Piston size

Three sizes of hexagonal pistons 1.27 cm, 1.59 cm, and 2.54 cm (½", **e** " and 1 ") were tested to determine if there is a correlation between the piston area and release rate. The force was adjusted to provide the same applied pressure (1.25 kg/cm^2) to the item under test. Table 1 shows an increase in the absolute migration rates (μg/hr) with increasing piston size, however, the rates were equivalent when expressed as rates per square centimeter of piston area (μg/hr/cm^2). Since actual tooth contact areas would vary by individual and age, the 5/8 inch piston was chosen to maintain consistency with the earlier ITRI study.

B. Characterization of phthalate release

1. Constancy of phthalate migration

The data plotted in Figure 5 shows that DINP migration rates for two separate samples remained relatively constant (1.3 ± 0.3 and 1.9 ± 0.2 μg/hr respectively) over four consecutive days of extractions. Phthalate migration could thus continue at the rates initially found over prolonged periods of time.

2. Replication of extraction by impaction

Extraction of two units each from four samples (Toy Fish, Tree House, Tiger Toy, and Pacifier) and extraction of five units each from two samples (Teether#3, and Toy Duck#2) provided data for assessing replication of migration. Table 2 shows that the average percent standard deviation for the combined six items was 17.05 percent (range 9.8 percent to 28.0 percent). Teether #3, which was relatively flat had the least variation (9.8 percent), and was tested intact. The toys and pacifier, however, were not flat and exhibited a greater variation. The greater variation with samples that were not flat may be due to non-uniform application of force over the surface of the item, flexing of the item when impacted, or other unknown factors.

3. Replenishment of saliva simulant and other migration media

These experiments examined the effect of replenishment on the amount of DINP that migrates from PVC products with various extraction media. Three different media were used, Dulbecco's buffer, Dulbecco's buffer with mucin added, and Dulbecco's buffer with mucin and sodium azide (a bacterial inhibitor). Each experiment listed in Table 3 used a separate unit of Toy Duck#2. The internal air bladder from each unit was cut into six sections, three for the 2 hour replenishment experiments and three for the 6 hour continuous experiments. After each replenishment, the medium that had been removed was treated with 50 ml of acetonitrile. After the third replenishment, the impaction beakers and impactors were washed with acetonitrile and the washings combined with the medium from the third extraction. The combined media and washings for each replenishment period were extracted with hexane. For comparison, a continuous six hour impaction experiment with no replenishment was also performed and the media extracted with hexane as described earlier. As shown in Table 3, the data are variable but the average total migration rate for all replenishment tests combined (41.4 μg/hr) is similar to that for all continuous tests (45.9 μg/hr) indicating that any replenishment effects, at least at 2 hour intervals, are small. The variability observed may reflect unknown differences in manufacturing or composition of each individual toy. The GC/MS ion chromatograms showed that not all of the products that appeared to be identical had the same distribution of DINP isomers. It is also not clear that the addition of mucin, or mucin and sodium azide increases phthalate extraction over buffer alone.

C. A survey of PVC children's products

A total of thirty five samples of children's products that were likely to be mouthed or chewed, were subjected to impaction in Dulbecco's phosphate buffered saline containing 0.16 percent mucin (Table 4). DINP was present in thirty one, DIOP in two, DEHP in one, and DnNP in one.

The phthalate release rate, calculated for 11 cm^2, ranged from 1.02 μg/hr to 48.40 μg/hr. Toy Duck #2 had the highest release rate of the thirty five samples tested (Table 4). This release rate was for an internal bladder (48.4 μg/hr). The release rate for exterior PVC from Toy Duck #2 was lower (6.4 μg/hr) . Figure 6 is a plot of the percentage of phthalate versus the release rate for the samples listed in Table 4. It clearly shows a lack of correlation between the release rate

and the amount of phthalate present in the samples. The reason for the lack of correlation is not known.

D. *In vivo* migration of phthalates

Table 5 presents the data from the *in vivo* migration study using PVC disks cut from the exterior of Toy Duck#2. The total quantities of saliva produced in four 15 minute periods of mouthing and chewing ranged from 27 ml to 95 ml. Saliva pH ranged from 6.90 to 7.66 with an average of 7.43. There was no apparent relationship between the amounts of phthalate migrating and the sex of the volunteers, the quantity of saliva produced, and the pH of the saliva. None of the saliva samples obtained from mouthing of the polytetrafluoroethylene control disks contained phthalates. The maximum migration rate for any one individual and time period was 826.48 μg/hr and the minimum was 32.78 μg/hr, a ratio of 25.2. Individuals showed better consistency in migration rates with the maximum to minimum migration rate ratios ranging from 1.57 to 3.10. The average migration rates for individuals ranged from 63.22 μg/hr to 596.64 μg/hr.

Table 6 presents the migration data obtained by impaction of new and the previously mouthed disks. A comparison of the impaction migration rates from new disks cut from the toy to impaction migration rates from disks used in the *in vivo* study show that the migration rates of the new disks are similar to the migration rates of the previously mouthed disks. The ratio of the geometric means of *the in vivo* migration rates to the *in vitro* migration rates of 39.5 showed that the impaction method substantially underestimates human exposure.

IV. Conclusions

DINP was the predominant phthalate found in children's products likely to be mouthed or chewed. Migration rates from impaction varied from 1 to 48 μg/hr/ll cm^2 and did not correlate well with phthalate content. The impaction method showed good repeatability overall and did not appear to be sensitive to buffer replenishment. The human subject study showed that the geometric mean migration rate from mouthing/chewing a new disk cut from a PVC children's toy was 39.5 times the geometric mean migration rate from impaction. Migration rates varied substantially from individual to individual.

Table 1. Variation of migration rates based on piston size.

Piston Size	% Phthalate	μg/hr	μg/hr/cm^2
1.27 cm (0.5 in)	29.96	2.97	2.14
		3.67	2.64
1.59 cm (0.62 in)	29.96	3.32	1.52
		2.41	1.11
		2.76	1.26
2.54 cm (1 in)	29.96	7.13	1.28
		9.07	1.63

Table 2. Replication of migration rates from the impaction method.

Sample	Description	Phthalate		Migration			
			% by wt	*μ*g/hr	Avg	Std. Dev.	% Deviation
1-8	Teether #3	DINP	43.28	7.38	8.25	0.81	9.78
1-8				7.88			
1-8				7.80			
1-8				8.98			
1-8				9.24			
2-2	Toy Duck #2	DINP	42.66	37.41	43.61	8.68	19.91
2-2				49.59			
2-2				43.18			
2-2				54.59			
2-2				33.28			
2-4	Toy Fish	DINP	36.95	10.59	11.71	1.58	13.47
2-4				12.82			
2-5	Tree House	DINP	36.05	14.64	13.56	1.53	11.26
2-5				12.48			
1-5	Tiger Toy	DINP	48.10	21.93	18.31	5.13	28.01
1-5				14.68			
1-13	Pacifier	DIOP	32.37	17.22	20.04	3.98	19.87
1-13				22.85			

Average % Deviation = 17.05% (Range 9.78% to 28.01%)

Table 3. Effect of replenishing the buffer vs 6 hours of continuous impaction with Toy Duck#2.

		DINP (μg)							
Media	**Time of Media Change**	**Migration with each 2 Hour Replenishment Sample Number**			**Average Total Migration**	**Migration, 6 hours continuous Impaction Sample Number**			**Average Total Migration**
	Hrs	**1**	**2**	**3**		**4**	**5**	**6**	
Dulbecco's	2	4.41	6.39	6.18					
Toy 2.01a	4	3.79	4.93	5.78					
	6	8.71	4.69	9.25					
Total Released		16.91	16.01	21.21	18.04	23.85	16.52	11.74	17.37
Dulbecco's	2	9.83	10.33	10.65					
Repeated	4	10.72	9.71	8.27					
Toy 2.01b	6	14.16	13.52	16.83					
		34.71	33.56	35.75	34.67	72.02	81.49	97.42	83.64
Dulbecco's	2	19.38	19.16	18.57					
and Mucin	4	16.15	21.54	21.82					
Toy 2.01c	6	21.41	20.28	27.29					
Total Released		56.94	60.98	67.68	61.87	61.6	50.48	32.3	48.12
Dulbecco's +	2	19.2	17.1	17.67					
Mucin + Na Azide	4	13.87	14.62	12.57					
Toy 2.01d	6	19.48	15.86	22.77					
Total Released		52.55	47.58	53.01	51.05	32.09	35.38	35.99	34.49
Average all replenishment tests			41.41			Average All Continuous tests			45.91

Table 4. Migration rates and calculated migration rate for 11 cm^2 of PVC samples.

Sample	Description	Phthalate	% by wt	Total Migration μg/hr	Area Immersed cm^2	Impact Migration $\mu g/hr/cm^2$	Non-impact Migration $\mu g/hr/cm^2$	Calculated Migration Rate[1] $\mu g/hr/11\ cm^2$
1.01	Handbag	DEHP	19.05	10.84	75	2.28	0.08	5.68
1.02	Book	DINP	27.45	5.40	75	1.14	0.0402	2.83
1.03	Teether#1	DINP	36.59	17.50	50	4.52	0.1599	11.26
1.04	Soother#1	DnNP	26.74	47.09	40	13.39	0.4734	33.36
1.05	Tiger Toy	DINP	48.1	21.93	75	4.61	0.1631	11.49
1.06	Toy Dolphin	DINP	43.66	33.45	20	11.90	0.4209	29.66
1.07	Teether#2	DINP	29.96	5.00	60	1.18	0.0419	2.94
1.08	Teether#3	DINP	43.28	8.98	40	2.55	0.0903	6.36
1.09	Teether#4	DINP	33.47	6.06	30	1.92	0.0677	4.77
1.10	Teether$5	DINP	54.43	7.55	50	1.95	0.0690	4.86
1.11	Corner Pads	DINP	43.98	18.22	25	6.10	0.2157	15.20
1.12	Nipple	DIOP	41.88	42.44	15	16.12	0.5698	40.16
1.13	Pacifier	DIOP	32.37	17.22	28	5.57	0.1969	13.87
1.14	Toy Food	DINP	51.00	24.35	20	8.67	0.3064	21.59
2.01	Toy Duck#1	DINP	40.81	3.85	16	1.44	0.0510	3.59
2.02	Toy Duck#2	DINP	42.66	54.59	20	19.43	0.6869	48.40
2.03	Teether#6	DINP	50.26	7.37	75	1.55	0.0548	3.86
2.04	Toy Fish	DINP	36.95	10.59	55	2.62	0.0925	6.51
2.05	Tree House	DINP	36.05	14.64	15	5.56	0.1966	13.85
2.07	Squeeze Toy #1	DINP	32.55	15.99	25	5.35	0.1893	13.34
2.08	Soother#2	DINP	30.17	2.83	75	0.60	0.0210	1.48
2.09	Teether#7	DINP	25.57	2.89	70	0.63	0.0223	1.57
2.10	Teether#8	DINP	19.29	3.55	25	1.19	0.0420	2.96
2.11	Book	DINP	17.45	2.69	75	0.57	0.0200	1.40
2.12	Bath Toy	DINP	15.14	1.95	75	0.41	0.0145	1.02
2.13	Toy Turtle	DINP	35.41	4.43	25	1.48	0.0524	3.69
2.14	Toy Bear	DINP	19.91	3.29	10	1.34	0.0474	3.33
2.15	Spoon#1	DINP	35.24	4.70	10	1.91	0.0676	4.76
2.16	Spoon#1	DINP	34.29	9.00	10	3.66	0.1295	9.12
3.01	Toy Ball	DINP	41.15	6.43	17	2.45	0.0739	5.93
3.02	Toy Bear	DINP	41.20	4.59	13	1.83	0.0553	4.46
3.03	Toy	DINP	27.08	2.72	7.5	1.16	0.0351	2.86
3.04	Toy Block	DINP	43.03	5.97	17	2.27	0.0686	5.5
3.05	Toy Car	DINP	42.68	2.47	12.5	0.99	0.0299	2.42
3.06	Squeeze Toy #2	DINP	42.49	3.17	18	1.19	0.0360	2.88

Note: One item tested, a suction cup (Toy # 2.06) with a hook for hanging things on windows is not included since it is not considered a children's product.

[1] The calculated migration rate for the assumed 11 cm^2 that is mouthed and chewed is the sum of the impaction piston area (2.18 cm^2) times the impaction migration rate and mouthed area (8.82 cm^2) times the non-impaction migration rate.

Table 5. ***In vivo*** **phthalate migration by mouthing and gentle chewing of 10.3 cm^2 disks (*μ*g/hr).**

	Subject									
Time (min)	**D1-1**	**D1-4**	**D2-1**	**D2-4**	**D3-1**	**D3-4**	**D4-1**	**D4-4**	**D5-1**	**D5-4**
15	48.22	248.34	510.86	257.60	207.48	101.50	388.74	143.72	250.30	420.98
30	101.54	379.30	371.62	184.34	249.62	109.20	464.00	193.84	152.44	322.62
45	70.36	153.84	559.18	559.18	246.86	67.64	826.48	216.76	272.18	143.26
60	32.78	243.78	336.32	235.76	159.34	81.74	707.34	229.36	214.24	261.24
Maximum	101.54	379.3	559.18	559.18	249.62	109.2	826.48	229.36	272.18	420.98
Minimum	32.78	153.84	336.32	184.34	159.34	67.64	388.74	143.72	152.44	143.26
Max/Min	3.10	2.47	1.66	3.03	1.57	1.61	2.13	1.60	1.79	2.94
Average for all time periods	63.23	256.32	444.50	309.22	215.83	90.02	596.64	195.92	222.29	287.03
Average of all humans		268.10								
Range of averages		63.23	to	596.64						
Saliva in ml	58	55	85	48	44	54	37	27	95	63
Saliva pH	7.13	7.55	7.65	7.61	7.48	7.47	7.21	6.90	7.66	7.62

Table 6. DINP migration by impaction of new and used disks from *in vivo* tests.

	Migration Rate			
	New disks		Used disks	
Disk number (DN)	**DN-2**	**DN-3**	**DN-1**	**DN-4**
	μg/hr	**μg/hr**	**μg/hr**	**μg/hr**
D1	9.53	4.43	4.72	5.02
D2	5.50	14.72	4.99	5.16
D3	4.61	4.86	3.78	5.21
D4	6.82	4.09	4.87	3.13
D5	6.84	2.49	4.84	8.07
Average	**6.66**	**6.12**	**4.64**	**5.32**

	New Disks	Used Disks
	μg/hr	μg/hr
Average of all new or used disks	6.39	4.98
Ratio of *in vivo*:Impaction[1]	39.50	

[1] The ratio is based on the geometric mean as described by M. A. Greene, Statistical methods for estimating average daily intake, U.S. Consumer Product Safety Commission, Washington, DC. December 1998.

Figure 1. Extraction apparatus

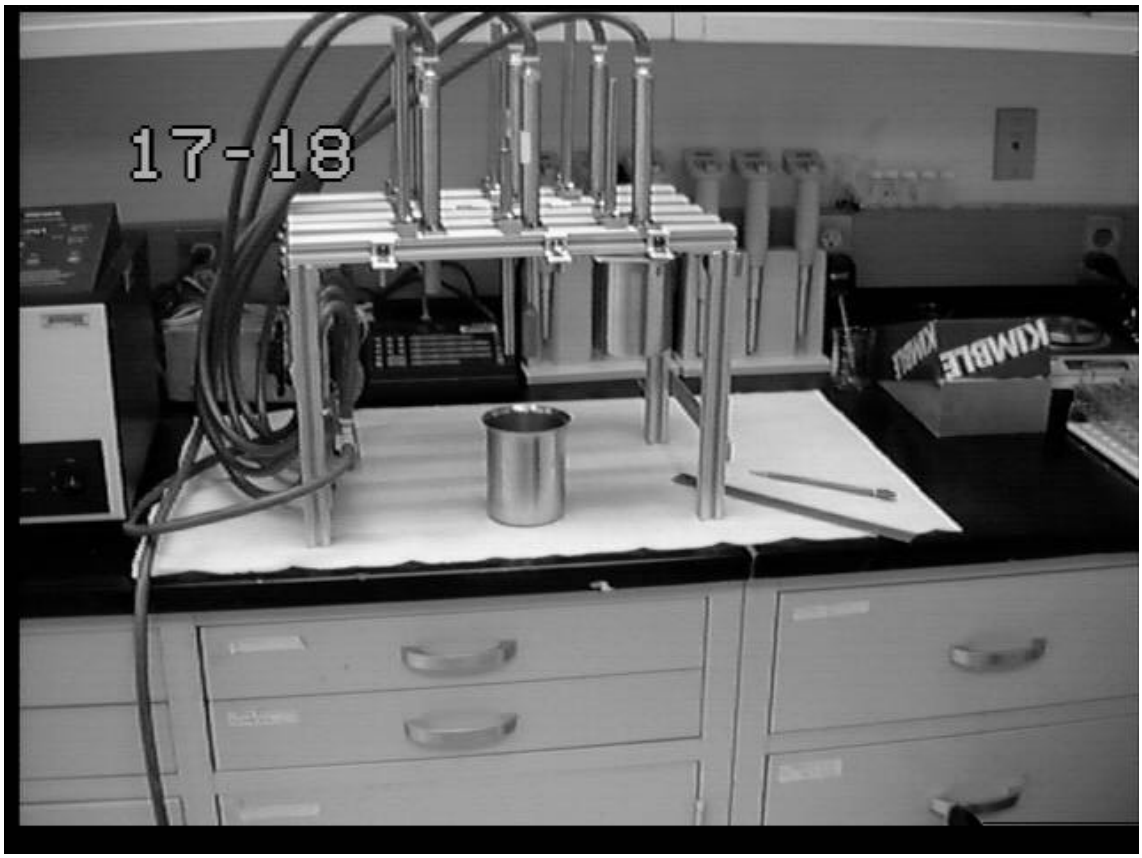


Figure 2. Extraction apparatus piston and hold down bar

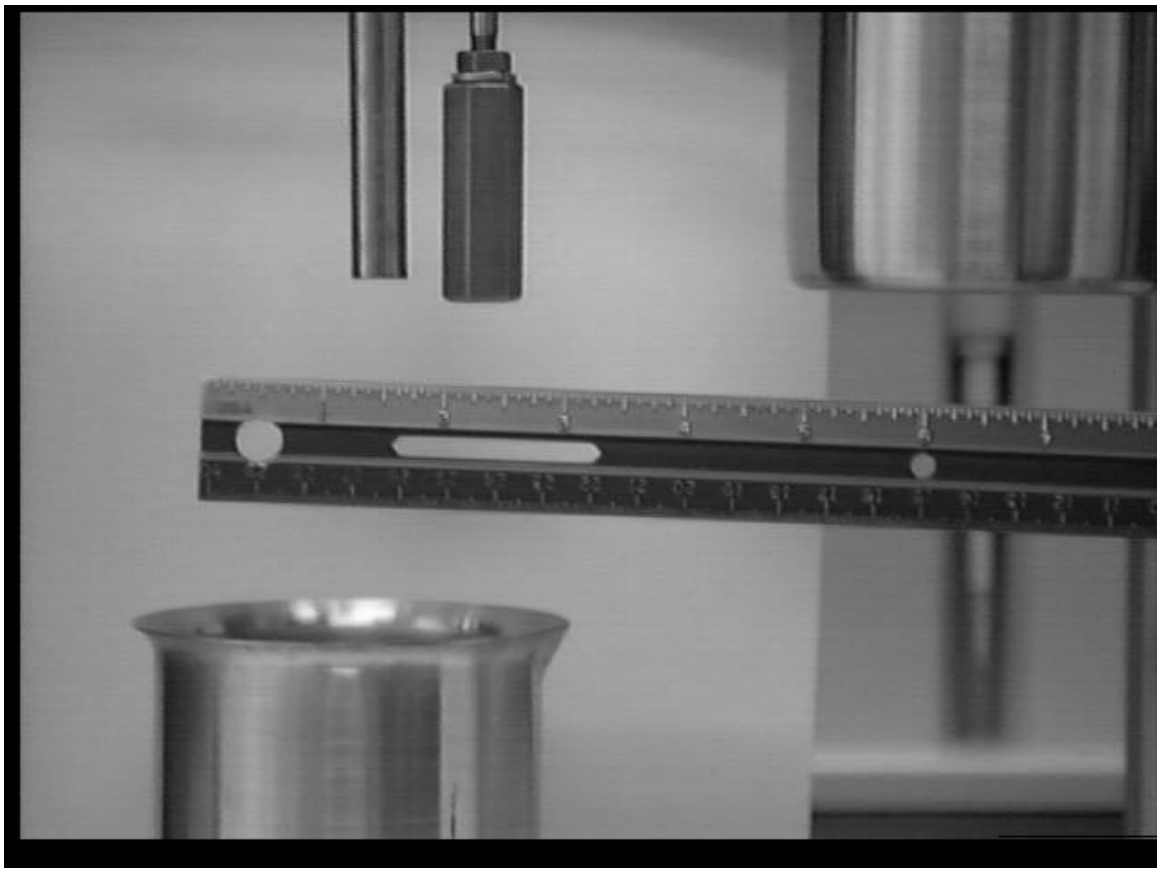


Figure 3. Migration rate vs force

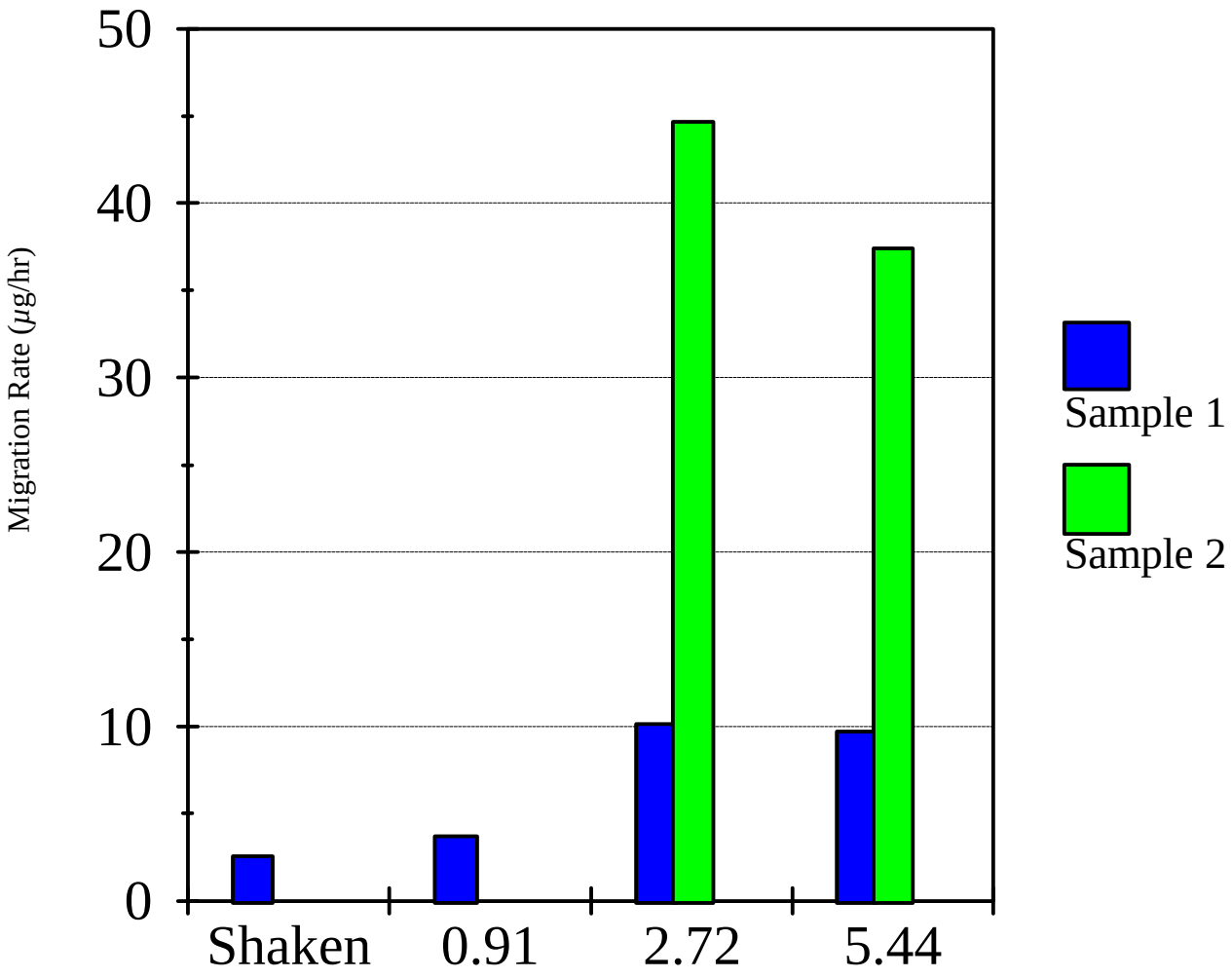


Figure 4. Variation of migration rates by length of impaction time

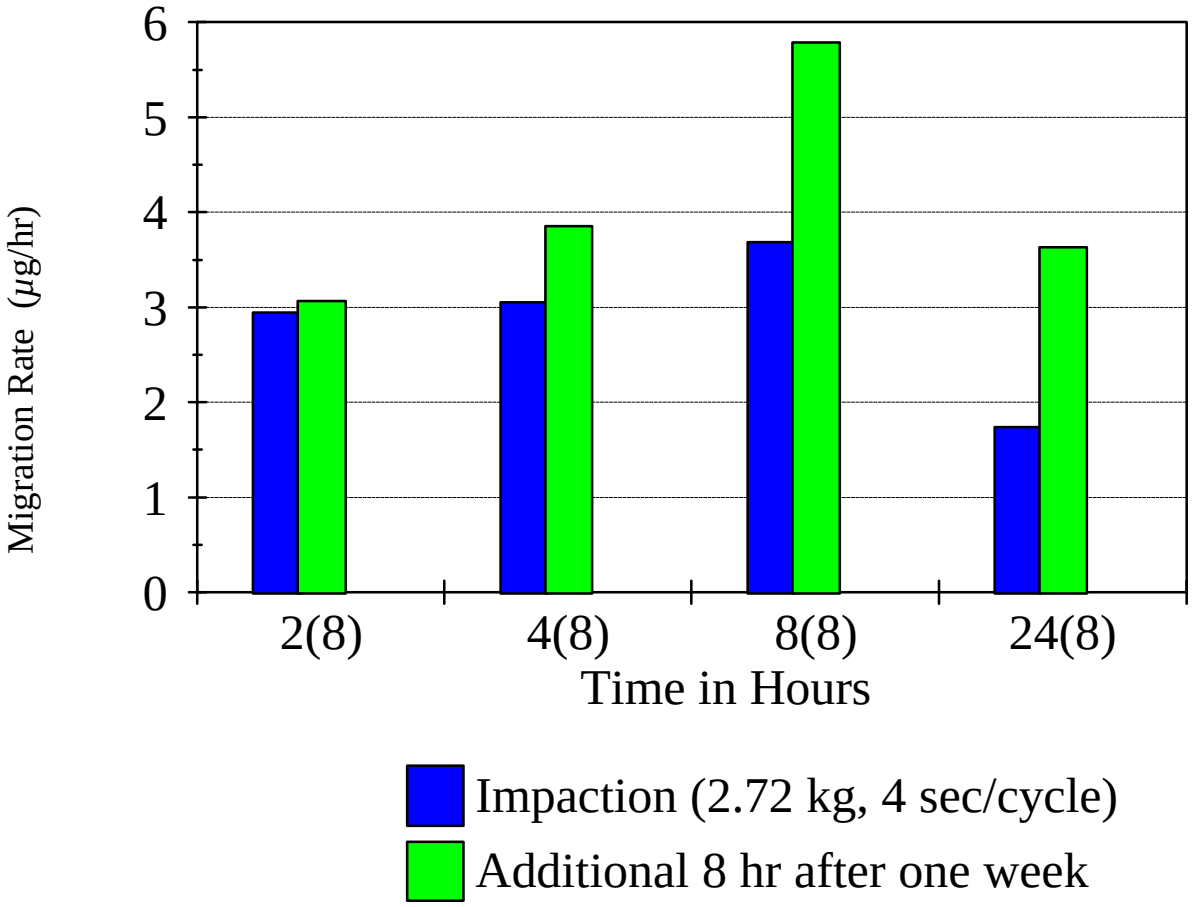


Figure 5. Migration rate on consecutive days, 4 seconds/cycle, 2.72 kg force, 6 hours

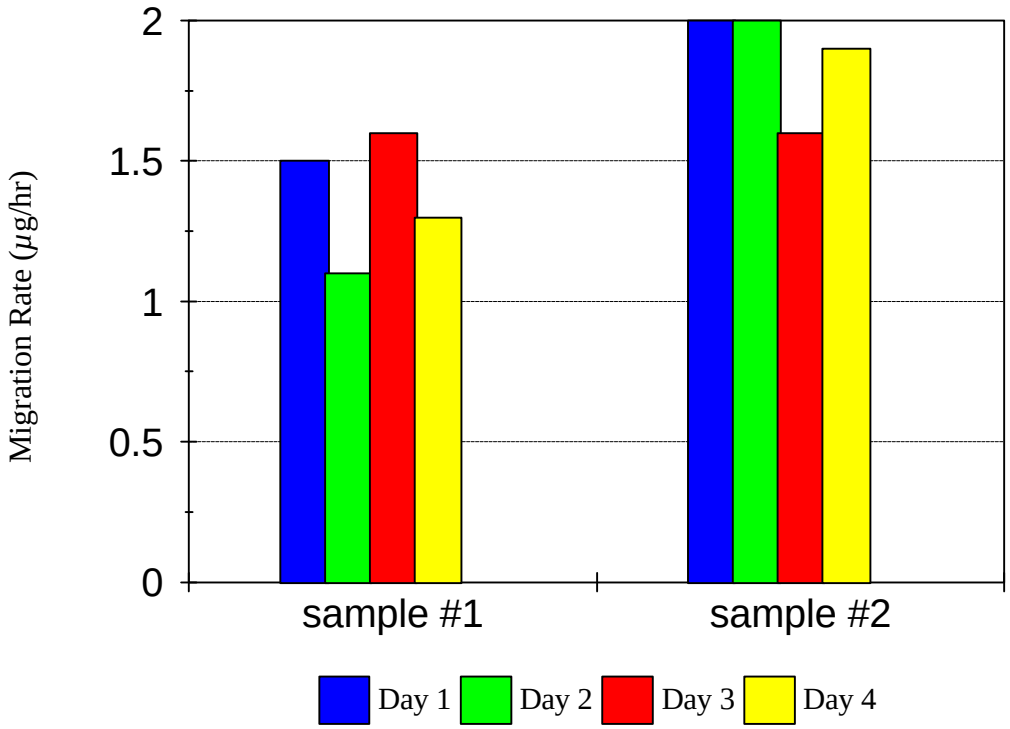
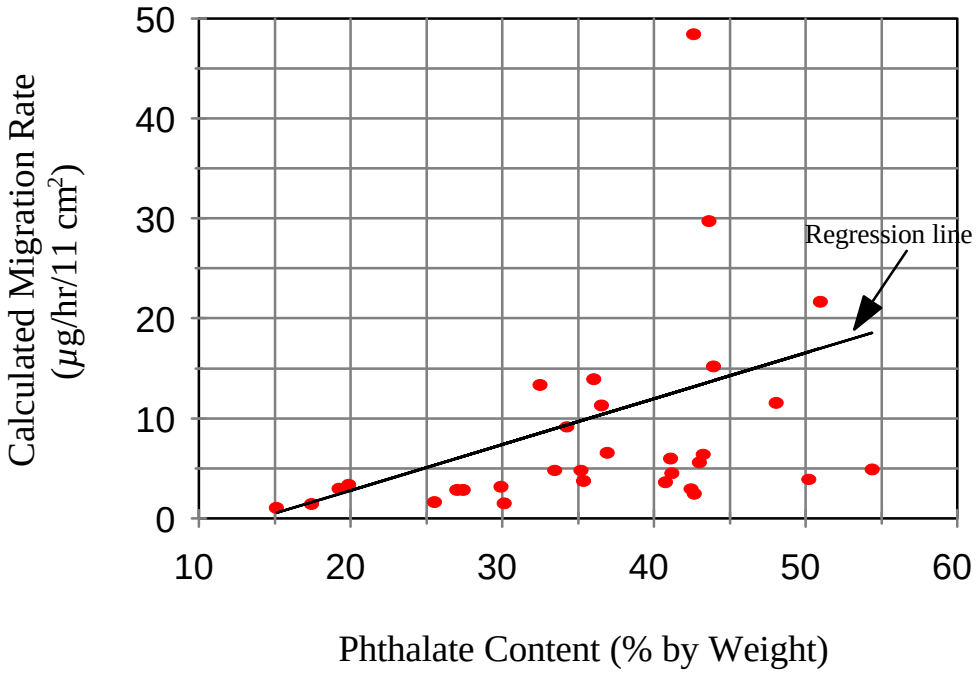


Figure 6. Calculated DINP migration vs % DINP



Note: The regression line has a slope of 0.37, and an R^2 of 0.143.