

Individual blood lead concentrations ($\mu\text{g/mL}$) in microswine

GROUP: A TEST SUBSTANCE: AEC 3-3

Collection Time (hrs)	Animal 1043	Animal 1071	Animal 987	Animal 1012	Mean	S.D.
0	0.005	0.010	0.007	0.067	0.02	0.03
0.5	0.099	0.158	0.231	0.450	0.23	0.15
1	0.227	0.120	0.386	0.511	0.31	0.17
2	0.301	0.823	0.431	0.488a	0.51	0.22
4	0.553a	0.382	0.603	0.407	0.49	0.11
8	0.206b	0.053	0.312a	0.242a	0.20	0.11
12	0.210	0.134	0.322c	0.199	0.22	0.08
24	0.605	0.302	0.375a	0.395	0.42	0.13
48	0.348	0.533	0.286	0.167	0.33	0.15
72	0.143	0.057	0.156a	0.214	0.14	0.07
96	0.106	0.102	0.196	0.093	0.12	0.05
120	0.058	0.086	0.080a	0.045	0.07	0.02
144	0.141	0.073a	0.092	0.182	0.12	0.05
192	0.076	0.057	0.087	0.051	0.07	0.02
240	0.055	0.050	0.058	0.054	0.05	0.00

GROUP: B TEST SUBSTANCE: AEC 9-3

Collection Time (hrs)	Animal 1033	Animal 986	Animal 1003	Animal 1027	Mean	S.D.
0	0.011	0.005	0.005	0.008	0.01	0.00
0.5	0.083	0.007b	0.051	0.167	0.08	0.07
1	0.145	0.017b	0.122	0.227	0.13	0.09
2	0.346	0.697c	0.400	0.296a	0.43	0.18
4	0.286	0.100	0.454	0.386	0.31	0.15
8	0.344	0.160	0.289	0.470	0.32	0.13
12	0.173	0.237	0.278	0.357	0.26	0.08
24	0.094b	0.240	0.193	0.283	0.20	0.08
48	0.088	0.148	0.159	0.121	0.13	0.03
72	0.085	0.091	0.095	0.190	0.12	0.05
96	0.054	0.099	0.074a	0.127	0.09	0.03
120	0.070	0.067	0.073	0.115	0.08	0.02
144	0.108	0.093	0.111	0.179	0.12	0.04
192	0.078	0.020	0.017	0.053	0.04	0.03
240	0.047	0.036	0.045	0.111	0.06	0.04

^a Analysis repeated; results from repeated analysis replace results from original analysis.

^b Analysis repeated; results from repeated analysis not used.

^c Analysis repeated twice; results from first repeated analysis replace results from original analysis.

Individual blood lead concentrations ($\mu\text{g/mL}$) in micsowine (continued).

GROUP: C						TEST SUBSTANCE: Lead Acetate	
Collection Time (hrs)	Animal 981	Animal 1064	Animal 1041	Animal 996	Animal 992	Mean	S.D.
0	0.008	0.005	0.005	0.011	0.005b	0.01	0.00
0.5	2.460	12.400b	2.700	1.030	0.138b	3.75	4.95
1	1.800	11.430b	4.330	0.218b	0.088a	3.57	4.71
2	2.370	3.660	2.670	0.430b	0.175b	1.86	1.50
4	0.538	1.990b	1.270b	0.326	0.205b	0.87	0.75
8	0.784	0.821	1.760b	0.569	0.809a	0.95	0.47
12	0.640	1.060	1.050	0.305	0.180b	0.65	0.41
24	0.497	0.946	0.795	0.349	0.133b	0.54	0.33
48	0.214	0.680	0.518	0.119	0.107a	0.33	0.26
72	0.329	0.512	0.359	0.134	0.129a	0.29	0.16
96	0.372	0.479	0.297	0.160	0.128a	0.29	0.15
120	0.266	0.388	0.283	0.124	0.066b	0.23	0.13
144	0.224	0.259	0.189	0.121	0.091a	0.18	0.07
192	0.181	0.272	0.231	0.076	0.043b	0.16	0.10
240	0.131	0.298	0.159	0.092	0.021b	0.14	0.10

GROUP: D						TEST SUBSTANCE: AEC 10-1	
Collection Time (hrs)	Animal 965	Animal 1052	Animal 972	Animal 1024	Animal 973	Mean	S.D.
0	0.005	0.005	0.042	0.005	0.005	0.01	0.02
0.5	0.041	0.005	0.008	0.111	0.128	0.06	0.06
1	0.075	0.005	0.074	0.173	0.251	0.12	0.10
2	0.114	0.005	0.095	0.338	0.205	0.15	0.13
4	0.282	0.095	0.283	0.804	0.624	0.42	0.29
8	0.161	0.328	0.260	0.403	0.191	0.27	0.10
12	0.182	0.300	0.160	0.338	0.196	0.24	0.08
24	0.160	0.391	0.241	0.264	0.263	0.26	0.08
48	0.144	0.193	0.199	0.193	0.210	0.19	0.03
72	0.088	0.170	0.148	0.209	0.173	0.16	0.05
96	0.094	0.136	0.126	0.169	0.122	0.13	0.03
120	0.055	0.093	0.076	0.136	0.063	0.08	0.03
144	0.022	0.076	0.055	0.111	0.062	0.07	0.03
192	0.047	0.054	0.041	0.078	0.075	0.06	0.02
240	0.051	0.055	0.037	0.059	0.050	0.05	0.01

^a Analysis repeated; results from repeated analysis replace results from original analysis.

^b Analysis repeated; results from repeated analysis not used.

^c Analysis repeated twice; results from first repeated analysis replace results from original analysis.

Individual blood lead concentrations ($\mu\text{g/mL}$) in micsowine (continued).**GROUP: E TEST SUBSTANCE: PLW**

Collection Time (hrs)	Animal 185	Animal 175	Animal 1255	Animal 1212	Animal 144	Animal 1251	Mean	S.D.
0	0.005	0.007	0.005	0.005	0.005	0.011	0.01	0.00
0.5	0.008	0.005	0.005	0.005	0.005	0.005	0.01	0.00
1	0.005	0.005	0.005	0.005	0.011	0.005	0.01	0.00
2	0.005	0.005	0.005	0.005	0.005	0.005	0.01	0.00
4	0.075	0.013	0.012	0.019	0.040	0.119	0.05	0.04
8	0.131	0.097	0.043	0.069	0.056	0.063	0.08	0.03
12	0.088	0.077	0.047	0.068	0.062	0.037	0.06	0.02
24	0.069	0.118	0.048	0.081	0.067	0.041	0.07	0.03
48	0.022	0.040	0.021	0.032	0.018	0.013	0.02	0.01
72	0.055	0.044	0.028	0.061	0.031	0.024	0.04	0.02
96	0.028	0.039	0.025	0.037	0.031	0.014	0.03	0.01
120	0.035	0.037	0.013	0.028	0.019	0.016	0.02	0.01
144	0.014	0.026	0.010	0.021	0.015	0.011	0.02	0.01
192	0.005	0.032	0.011	0.032	0.008	0.026	0.02	0.01
240	0.032	0.018	0.017	0.033	0.020	0.017	0.02	0.01

GROUP: G TEST SUBSTANCE: EC1

Collection Time (hrs)	Animal 1191	Animal 1241	Animal 1242	Animal 1246	Animal 145	Animal 196	Mean	S.D.
0	0.045	0.048	0.038	0.034	0.040	0.033	0.04	0.01
0.5	0.042	0.046	0.052	0.052	0.067	0.026	0.05	0.01
1	0.044	0.021	0.048	0.050	0.055	0.060	0.05	0.01
2	0.046	0.054	0.055	0.048	0.031	0.050	0.05	0.01
4	0.051	0.053	0.039	0.057	0.070	0.062	0.06	0.01
8	0.058	0.097	0.049	0.060	0.046	0.052	0.06	0.02
12	0.102	0.120	0.107	0.087	0.077	0.079	0.10	0.02
24	0.083	0.191	0.187	0.176	0.128	0.155	0.15	0.04
48	0.112	0.106	0.124	0.098	0.067	0.082	0.10	0.02
72	0.061	0.067	0.082	0.102	0.055	0.061	0.07	0.02
96	0.061	0.061	0.063	0.094	0.059	0.081	0.07	0.01
120	0.042	0.079	0.074	0.097	0.077	0.069	0.07	0.02
144	0.042	0.056	0.065	0.082	0.026	0.055	0.05	0.02
192	0.033	0.057	0.063	0.065	0.061	0.054	0.06	0.01
240	0.054	0.049	0.076	0.064	0.084	0.066	0.07	0.01

Individual blood lead concentrations ($\mu\text{g/mL}$) in micsowine (continued).

GROUP: H						TEST SUBSTANCE: FM	
Collection Time (hrs)	Animal 452	Animal 404	Animal 453	Animal 442	Animal 423	Mean	S.D.
0	0.005	0.011	0.005	0.005	0.005	0.01	0.00
0.5	0.009	0.010	0.010	0.008	0.011	0.01	0.00
1	0.027	0.009	0.020	0.005	0.033	0.02	0.01
2	0.060	0.005	0.034	0.005	0.059	0.03	0.03
4	0.247	0.029	0.130	0.043	0.174	0.12	0.09
8	0.130	0.070	0.113	0.045	0.156	0.10	0.05
12	0.175	0.086	0.089	0.091	0.103	0.11	0.04
24	0.152	0.068	0.072	0.064	0.068	0.08	0.04
48	0.080	0.035	0.028	0.030	0.045	0.04	0.02
72	0.055	0.015	0.021	0.013	0.018	0.02	0.02
96	0.061	0.015	0.028	0.013	0.022	0.03	0.02
120	0.045	0.014	0.017	0.021	0.017	0.02	0.01
144	0.048	0.011	0.024	0.021	0.026	0.03	0.01
192	0.035	0.008	0.021	0.015	0.007	0.02	0.01
240	0.021a	0.015a	0.038a	0.015a	0.027a	0.02	0.01

GROUP: I						TEST SUBSTANCE: Lead Acetate	
Collection Time (hrs)	Animal 405	Animal 456	Animal 422	Animal 381	Animal 454	Mean	S.D.
0	0.013	0.014	0.010	0.013	0.006	0.01	0.00
0.5	0.441	0.037	0.162	0.529	0.223	0.28	0.20
1	0.529	0.075	0.133	0.469	0.166	0.27	0.21
2	0.509	0.177	0.258	0.336	0.344	0.32	0.12
4	0.167	0.046	0.127	0.302	0.225	0.17	0.10
8	0.209	0.052	0.152	0.232	0.190	0.17	0.07
12	0.224	0.035	0.112	0.148	0.139	0.13	0.07
24	0.164	0.060	0.093	0.098	0.142	0.11	0.04
48	0.113	0.037	0.074	0.083	0.108	0.08	0.03
72	0.096	0.042	0.059	0.108	0.112	0.08	0.03
96	0.074	0.041	0.045	0.070	0.072	0.06	0.02
120	0.064	0.027	0.058	0.043	0.052	0.05	0.01
144	0.056	0.016	0.041	0.064	0.034	0.04	0.02
192	0.040	0.026	0.044	0.041	0.046	0.04	0.01
240	0.070	0.024	0.053	0.035	0.050	0.05	0.02

^a Analysis repeated; results from repeated analysis replace results from original analysis.

Individual blood lead concentrations (ug/mL) in micsowine (continued).

		GROUP: J TEST SUBSTANCE: PLW1						
Collection Time (hrs)	Animal 394	Animal 455	Animal 443	Animal 451	Animal 401		Mean	S.D.
0	0.005	0.005	0.005	0.005	0.005		0.01	0.00
0.5	0.019	0.780	0.195	0.088	0.443		0.31	0.31
1	0.029	1.758	0.123	0.064	1.167		0.63	0.79
2	0.132	1.439	0.308	0.597	0.979		0.69	0.53
4	0.079	0.493	0.296	0.288	0.547		0.34	0.19
8	0.214	0.366	0.282	0.685	0.375		0.38	0.18
12	0.154	0.412	0.219	0.357	0.328		0.29	0.11
24	0.251	0.614	0.328	0.459	0.388		0.41	0.14
48	0.340	0.421	0.641	0.418	0.861		0.54	0.21
72	0.159	0.200	0.083	0.135	0.096		0.13	0.05
96	0.043	0.071	0.056	0.043	0.070		0.06	0.01
120	0.036	0.054	0.041	0.034	0.038		0.04	0.01
144	0.039	0.069	0.054	0.025	0.071		0.05	0.02
192	0.017	0.065	0.047	0.030	0.048		0.04	0.02
240	0.007	0.067	0.040	0.023	0.061		0.04	0.03

APPENDIX D. Individual body weights (g) of microswine.

The table below correlates the animal numbering system used in the study to the numbering system used to label the blood collection data.

Group Designation	Test Soil	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number
A	AEC 3-3	101	1043	102	1071	103	987	104	984	105	1012		
B	AEC 9-3	201	1033	202	986	203	1003	204	1094	205	1027		
C	Pb Acetate	301	981	302	1064	303	1041	304	996	305	992		
D	AEC 10-1	401	965	402	1052	403	972	404	1024	405	973		
E	PLW	101	185	102	175	103	1255	104	1212	105	144	106	1251
G	EC1	301	1191	302	1241	303	1242	304	1246	305	145	306	196
H	FM	101	452	102	404	103	453	104	442	105	423		
I	Pb Acetate	201	405	202	456	203	422	204	381	205	454		
J	PLW1	301	394	302	455	303	443	304	451	305	401		

Individual body weights (g) of microswine.

		GROUP: A		TEST SUBSTANCE: AEC 3-3	
Days on Test:	1	3	7	11	
Animal Number					
1043	4801.0	5047.0	5688.0	6409.0	
1071	6074.0	6212.0	6576.0	7535.0	
987	7264.0	7367.0	7947.0	9129.0	
984	8031.0	Sacrificed in extremis (DAY 2)			
1012	5206.0	5358.0	5873.0	6551.0	

		GROUP: B		TEST SUBSTANCE: AEC 9-3	
Days on Test:	1	4	6	10	11
Animal Number					
1033	6285.0	6700.0	7020.0	7370.0	7557.0
986	7132.0	7645.0	8034.0	8648.0	9005.0
1003	9532.0	9868.0	10460.0	10870.0	11220.0
1094	5781.0	Accidentally Killed (DAY 1)			
1027	6051.0	6333.0	6824.0	7274.0	7500.0

		GROUP: C		TEST SUBSTANCE: Lead Acetate	
Days on Test:	1	9	11		
Animal Number					
981	9768.0	11422.0	11662.0		
1064	5191.0	6717.0	7050.0		
1041	6580.0	8195.0	8491.0		
996	7879.0	9471.0	9768.0		
992	8250.0	9852.0	10143.0		

Individual body weights (g) of microswine (continued).

		GROUP: D		TEST SUBSTANCE: AEC 10-1	
Days on Test:	1	6	8	11	
Animal Number					
965	7954.0	8799.0	8933.0	9727.0	
1052	3628.0	4816.0	5292.0	5863.0	
972	9833.0	10394.0	10798.0	11217.0	
1024	6849.0	7798.0	8025.0	8709.0	
973	7593.0	8257.0	8443.0	8963.0	

		GROUP: E		TEST SUBSTANCE: PLW	
Days on Test:	1	4	8	11	
Animal Number					
185	6169.0	6704.0	7465.0	7734.0	
175	7256.0	7611.0	8289.0	8792.0	
1255	6055.0	6336.0	6953.0	7210.0	
1212	6175.0	6564.0	7124.0	7486.0	
144	7904.0	8333.0	8934.0	9371.0	
1251	5882.0	6159.0	6689.0	6914.0	

		GROUP: G		TEST SUBSTANCE: EC1	
Days on Test:	1	4	7	11	
Animal Number					
1191	7987.0	8351.0	8704.0	9290.0	
1241	8341.0	8608.0	9199.0	9483.0	
1242	6391.0	6694.0	7126.0	7597.0	
1246	7400.0	7831.0	8322.0	9023.0	
145	9279.0	9543.0	9903.0	10395.0	
196	6818.0	7285.0	7797.0	8408.0	

Individual body weights (g) of microswine (continued).

		GROUP: H		TEST SUBSTANCE: FM	
Days on Test:	1	3	7	11	
Animal Number					
452	7089.0	7438.0	7933.0	8610.0	
404	5958.0	6405.0	6929.0	7313.0	
453	5823.0	6198.0	6660.0	7384.0	
442	6566.0	6838.0	7189.0	7847.0	
423	5189.0	5525.0	6102.0	6711.0	

		GROUP: I		TEST SUBSTANCE: Lead Acetate	
Days on Test:	1	4	8	11	
Animal Number					
405	6867.0	7257.0	8086.0	8483.0	
456	6558.0	6993.0	7612.0	8029.0	
422	6288.0	6653.0	7428.0	7998.0	
381	6189.0	6490.0	7232.0	7830.0	
454	7100.0	7379.0	7988.0	8252.0	

		GROUP: J		TEST SUBSTANCE: PLW1	
Days on Test:	1	4	7	11	
Animal Number					
394	4464.0	5107.0	5629.0	6330.0	
455	6869.0	7397.0	7841.0	8502.0	
443	7586.0	7966.0	8244.0	8720.0	
451	6867.0	7182.0	7529.0	8162.0	
401	6420.0	6886.0	7290.0	7870.0	

APPENDIX E. Individual clinical observations in microswine.

The table below correlates the animal numbering system used in the study to the numbering system used to label the blood collection data.

Group Designation	Test Soil	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number
A	AEC 3-3	101	1043	102	1071	103	987	104	984	105	1012		
B	AEC 9-3	201	1033	202	986	203	1003	204	1094	205	1027		
C	Pb Acetate	301	981	302	1064	303	1041	304	996	305	992		
D	AEC 10-1	401	965	402	1052	403	972	404	1024	405	973		
E	PLW	101	185	102	175	103	1255	104	1212	105	144	106	1251
G	EC1	301	1191	302	1241	303	1242	304	1246	305	145	306	196
H	FM	101	452	102	404	103	453	104	442	105	423		
I	Pb Acetate	201	405	202	456	203	422	204	381	205	454		
J	PLW1	301	394	302	455	303	443	304	451	305	401		

Individual clinical observations in microswine.

GROUP: A TEST SUBSTANCE: AEC 3-3

Animal Number	Observation	First Day Observed	Last Day Observed
1043	No Abnormalities Detected Sacrificed by Design Test Day 11		
1071	No Abnormalities Detected Sacrificed by Design Test Day 11		
987	No Abnormalities Detected Sacrificed by Design Test Day 11		
984	No Abnormalities Detected Sacrificed <i>in extremis</i> Test Day 2		
1012	No Abnormalities Detected Sacrificed by Design Test Day 11		

GROUP: B TEST SUBSTANCE: AEC 9-3

Animal Number	Observation	First Day Observed	Last Day Observed
1033	No Abnormalities Detected Sacrificed by Design Test Day 11		
986	No Abnormalities Detected Sacrificed by Design Test Day 11		
1003	No Abnormalities Detected Sacrificed by Design Test Day 11		
1094	No Abnormalities Detected Accidentally Killed Test Day 1		
1027	No Abnormalities Detected Sacrificed by Design Test Day 11		

Individual clinical observations in microswine (continued).

GROUP: C		TEST SUBSTANCE: Lead Acetate	
Animal Number	Observation	First Day Observed	Last Day Observed
981	No Abnormalities Detected Sacrificed by Design Test Day 11		
1064	No Abnormalities Detected Sacrificed by Design Test Day 11		
1041	No Abnormalities Detected Sacrificed by Design Test Day 11		
996	No Abnormalities Detected Sacrificed by Design Test Day 11		
992	No Abnormalities Detected Sacrificed by Design Test Day 11		

GROUP: D		TEST SUBSTANCE: AEC 10-1	
Animal Number	Observation	First Day Observed	Last Day Observed
965	No Abnormalities Detected Sacrificed by Design Test Day 11		
1052	Diarrhea Sacrificed by Design Test Day 11	8	8
972	No Abnormalities Detected Sacrificed by Design Test Day 11		
1024	No Abnormalities Detected Sacrificed by Design Test Day 11		
973	No Abnormalities Detected Sacrificed by Design Test Day 11		

Individual clinical observations in microswine (continued).

GROUP: E		TEST SUBSTANCE: PLW	
Animal Number	Observation	First Day Observed	Last Day Observed
185	No Abnormalities Detected Sacrificed by Design Test Day 11		
175	No Abnormalities Detected Sacrificed by Design Test Day 11		
1255	No Abnormalities Detected Sacrificed by Design Test Day 11		
1212	No Abnormalities Detected Sacrificed by Design Test Day 11		
144	No Abnormalities Detected Sacrificed by Design Test Day 11		
1251	No Abnormalities Detected Sacrificed by Design Test Day 11		

GROUP: G		TEST SUBSTANCE: EC1	
Animal Number	Observation	First Day Observed	Last Day Observed
1191	No Abnormalities Detected Sacrificed by Design Test Day 11		
1241	No Abnormalities Detected Sacrificed by Design Test Day 11		
1242	No Abnormalities Detected Sacrificed by Design Test Day 11		
1246	No Abnormalities Detected Sacrificed by Design Test Day 11		
145	No Abnormalities Detected Sacrificed by Design Test Day 11		
196	No Abnormalities Detected Sacrificed by Design Test Day 11		

Individual clinical observations in microswine (continued).

GROUP: H TEST SUBSTANCE: FM

Animal Number	Observation	First Day Observed	Last Day Observed
452	No Abnormalities Detected Sacrificed by Design Test Day 11		
404	Bent Right Front Paw(s) Sacrificed by Design Test Day 11	1	11 NR
453	No Abnormalities Detected Sacrificed by Design Test Day 11		
442	No Abnormalities Detected Sacrificed by Design Test Day 11		
423	No Abnormalities Detected Sacrificed by Design Test Day 11		

GROUP: I TEST SUBSTANCE: Lead Acetate

Animal Number	Observation	First Day Observed	Last Day Observed
405	No Abnormalities Detected Sacrificed by Design Test Day 11		
456	No Abnormalities Detected Sacrificed by Design Test Day 11		
422	No Abnormalities Detected Sacrificed by Design Test Day 11		
381	No Abnormalities Detected Sacrificed by Design Test Day 11		
454	No Abnormalities Detected Sacrificed by Design Test Day 11		

Individual clinical observations in microswine (continued).

GROUP: J TEST SUBSTANCE: PLW1

Animal Number	Observation	First Day Observed	Last Day Observed
394	No Abnormalities Detected Sacrificed by Design Test Day 11		
455	No Abnormalities Detected Sacrificed by Design Test Day 11		
443	No Abnormalities Detected Sacrificed by Design Test Day 11		
451	No Abnormalities Detected Sacrificed by Design Test Day 11		
401	No Abnormalities Detected Sacrificed by Design Test Day 11		

APPENDIX F Sample calculations

1. Sample calculation for the amount of lead in the dose.

Formula:

Concentration of Lead (ppm) x Gavage Sample (g) x Dilution Factor = Lead in Sample (mg)

Example: Soil PLW

Mean lead analyzed = 244.5 ppm

Gavage sample = 21.17 g soil + 30 g water = 51.17 g

Dilution factor = 0.75

Concentration of lead derived from analysis during the study.

Soil weight (21.17 g) was calculated in order to give each animal 17 mg of lead. This soil lead concentration is 803 ppm (information obtained from the study sponsor). The dose was prepared for 10 animals.

211.7 g soil was weighed and mixed with 300 mL water; 30 mL of the mixture was given to each animal. In some cases, the soil did not mix well, so the amount of water was increased to 400 or 500 mL. This additional water is the reason for the dilution factor used in the calculations.

$$\begin{aligned} 244.5 \text{ ppm} \times 51.17 \text{ g} \times 0.75 &= \text{lead in sample (mg)} \\ 0.2445 \text{ mg/g} \times 51.17 \text{ g} \times 0.75 &= \text{lead in sample (mg)} \\ 9.383 \text{ mg} &= \text{lead in sample} \end{aligned}$$

2. Sample calculation for area under the curve (AUC).

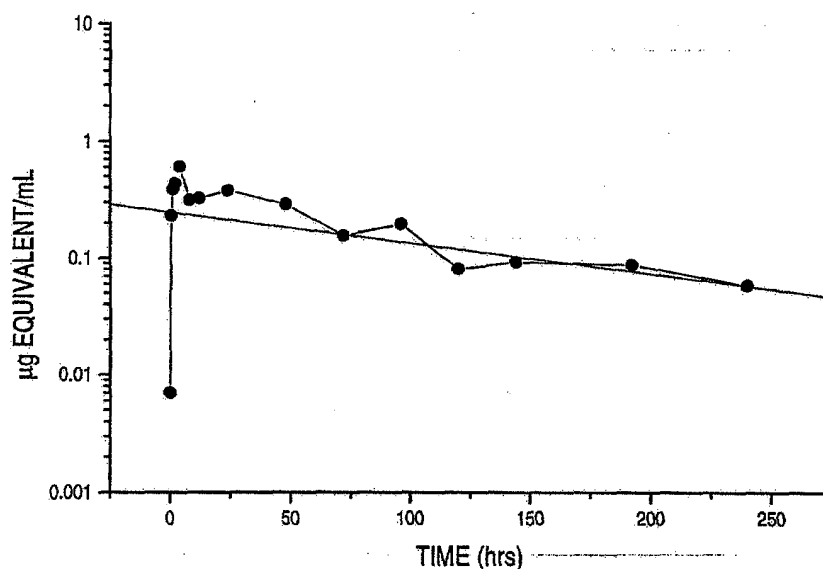
Formulas:

$$\text{Slope} = -\beta / 2.303$$

$$\text{Area } \infty = \text{Value of Last Time Point} / \beta$$

$$\text{Total AUC} = \text{Area} + \text{Area } \infty$$

Example: Plasma Data from Animal #987, Group A (AEC 3-3)



$$\text{Area} = 39.54825$$

$$B (\text{slope} \pm \text{std.dev.}) = -0.00264 \pm 0.00121$$

$$\text{Concentration at Last Time Point} = 0.058 \mu\text{g/mL}$$

$$\text{Slope} = -\beta / 2.303$$

$$-0.00264 = -\beta / 2.303$$

$$-0.00264 \times 2.303 = -\beta$$

$$0.0060799 = \beta$$

$$\text{Area } \infty = 0.058 / \beta$$

$$\text{Area } \infty = 0.058 / 0.0060799$$

$$\text{Area } \infty = 9.5396306$$

$$\text{Total AUC} = \text{Area} + \text{Area } \infty$$

$$\text{Total AUC} = 39.54825 + 9.5396306$$

$$\text{Total AUC} = 49.087881 \mu\text{g}(\text{hr})/\text{mL}$$

APPENDIX G. Lead analyses reports.

The table below correlates the animal numbering system used in the study to the numbering system used to label the blood collection data.

Group Designation	Test Soil	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number	Blood Sample Label	Animal Number
A	AEC 3-3	101	1043	102	1071	103	987	104	984	105	1012	106 1251 306 196	
B	AEC 9-3	201	1033	202	986	203	1003	204	1094	205	1027		
C	Pb Acetate	301	981	302	1064	303	1041	304	996	305	992		
D	AEC 10-1	401	965	402	1052	403	972	404	1024	405	973		
E	PLW	101	185	102	175	103	1255	104	1212	105	144		
G	EC1	301	1191	302	1241	303	1242	304	1246	305	145		
H	FM	101	452	102	404	103	453	104	442	105	423		
I	Pb Acetate	201	405	202	456	203	422	204	381	205	454		
J	PLW1	301	394	302	455	303	443	304	451	305	401		

Lead Analysis Report #1: Soils AEC 3-3, AEC 9-3, and AEC 10-1

Analysis of Pb in Blood, Soil, and Associated Materials
in Support of Haskell Lab Medical Research Project No. MR 9727-001

Author

Keith A. McCleary

Study Completed:

1/26/94

Performed By:

DuPont Specialty Chemicals

Trace Metals Analysis Group

Quality Control Laboratory

Chambers Works

Deepwater, NJ 08023

Signature: Keith A. McCleary
Keith A. McCleary, Ph.D.

Date 6/10/94

Lead Analysis Report #1: Soils AEC 3-3, AEC 9-3, and AEC 10-1

Summary

The purpose of this study was to determine the amount of lead that was contained in samples associated with MR9727-001. There were essentially three type of samples: blood (microswine), aqueous (drinking water, dosing solutions), and solid (soil, bedding, etc.). Blood samples were prepared by dilution with a modifier solution (to digest sample and break viscosity) and analyzed using Graphite Furnace Atomic Absorption Spectrometry (GFAAS). Aqueous and solid samples were prepared using microwave assisted digestion and analyzed using Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES). All samples were run in duplicate and average answers reported. In the case of the blood, each sample and duplicate was spiked and checked for recovery. If the spike recovery was greater than 10% in error, a one point standard additions calculation was performed.

Methodology

The descriptions listed below are summaries of the actual methods used to analyze samples. The actual methods are documented in the GLP Protocols Notebook, archived at QCL and copies are available upon request.

Sample Preparation: Blood

Blood samples were received in small polyethylene vials. Approximate sample volume was 100-300 uL. 100 uL of blood is diluted to 1.0 mL with modifier solution. The modifier solution is a solution of nitric acid (digests sample), Triton X-100 (surfactant, breaks viscosity), methanol (antifoaming agent), and ammonium phosphate (GFAAS modifier) in water.

Sample Analysis: Blood

Blood samples are analyzed using Graphite Furnace Atomic Absorption Spectrometry (GFAAS). In GFAAS, a 20 microliter volume of sample + modifier is injected into a small graphite tube. This tube is electromagnetically heated to dry, char, and atomize the sample. A hollow cathode lamp (HCL) shines light corresponding to the atomic emission of Pb (283.3 nm) through the tube. As free Pb atoms are generated by the sample atomization, they absorb the radiation, attenuating the amount of signal from the HCL. The degree of attenuation of the HCL radiation is proportional to the concentration of Pb in the sample. Calibration standards of 10, 20, and 30 ng/mL are prepared by serial dilution of a 1000 ug/mL stock. Each blood sample is analyzed twice. Each sample and duplicate is then spiked with 10ng Pb and reanalyzed to check for recovery. If recovery is less than 90% or greater than 110%, a one point standard addition calculation is

Lead Analysis Report #1: Soils AEC 3-3, AEC 9-3, and AEC 10-1

performed to determine the amount of Pb in the sample. Each result is the average of the two replicates.

Sample Preparation: Aqueous Samples

Samples that are primarily aqueous are prepared by acidifying 10.00 mL of sample with 2.00 mL concentrated HNO₃. The sample is then diluted to a final volume of 20.00 mL and analyzed by ICP-AES.

Sample Preparation: Solid Samples

Solid Samples are prepared by microwave assisted digestion. 0.1 - 0.2 g of sample are digested with 5.00 mL concentrated HNO₃ in a Teflon lined pressure vessel. The vessels are placed in a microwave digestion apparatus and cooked for 10 minutes at 300@W power. The samples are allowed to cool and are then filtered into a 50 mL volumetric flask and diluted to volume with deionized water. Samples are analyzed for Pb content by ICP-AES.

Sample Analysis : Aqueous and Solid Samples

These samples are analyzed by Inductively Coupled Plasma - Atomic Emission Spectrometry (ICP-AES). The prepared samples are pumped into a sample introduction system where a fine spray of aerosol is generated. This sample aerosol flows along a stream of argon gas into the plasma. The plasma is a highly energetic discharge sustained in argon by applied radio-frequency power in excess of 1000 W. This discharge is energetic enough to desolvate, atomize, and excite the sample species to radiative emission. The intensity of the characteristic emission wavelength of Pb (220.35 nm) is proportional to the amount of Pb in the sample.

Results

The results for all samples submitted under MR9727-001 are listed in Appendix I.

Lead Analysis Report #1: Soils AEC 3-3, AEC 9-3, and AEC 10-1

PB_PHS2.XLS
MR 9727-001

TIME (hrs)	GROUP (A)	GROUP (B)	TIME (hrs)	GROUP (C)	GROUP (D)
101	102	201	103	202	203
ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL
10	10	11	7	8	8
Predose	Predose	Predose	Predose	Predose	Predose
0.5	158	83	0.5	145	7
1	227	1	1	145	17
2	301	3190	2	348	2740
4	1110	382	4	286	100
8	206	603	8	344	180
12	210	61	12	173	237
24	605	32	24	94	240
48	348	1447	48	88	193
72	143	286	72	85	159
96	106	102	96	64	91
120	88	135	120	70	99
144	141	1073	144	108	67
192	76	87	192	78	83
240	55	58	240	47	20
TIME (hrs)	GROUP (A)	GROUP (B)	TIME (hrs)	GROUP (C)	GROUP (D)
301	302	401	303	402	403
ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL
8	8	8	11	8	42
Predose	Predose	Predose	Predose	Predose	Predose
0.5	2460	12400	0.5	41	111
1	1800	11430	1	75	8
2	2370	3680	2	114	74
4	538	1990	4	282	95
8	784	821	8	161	283
12	840	1080	12	182	260
24	497	948	24	180	300
48	214	680	48	144	391
72	329	512	72	88	193
96	372	479	96	94	170
120	266	388	120	55	136
144	224	259	144	22	76
192	181	272	192	47	55
240	131	298	240	51	41
				51	37
				55	59
				50	50

Page 1 OF 2

PB_PHS2.XLS
MR 9727-001

REPEATS (ng/mL)				NON BLOOD SAMPLES (ug/mL)			
Time	C305 RPT			AEC10-1			
predose	<5					516	
0.5	84	C302-0.5	17800			513	
1	88	C302-1	12130			686	
2	141	C304-1	670	AEC 9-3		1686	
4	169	C304-2	200			1776	
8	809	C302-4	1870			1411	
12	175	C303-4	1670	AEC 3-3		884	
24	54	C303-8	1070			803	
48	107					596	
72	129			PIG DOSE I (AEC 3-3)		763	
96	128			PIG DOSE II (AEC 3-3)		521	
120	58			GRPII 202		1962	
144	91			GRPII 203		1306	
192	30			GRPII 205		1116	
240	17			#401		385	
				#402		636	
				#403		985	
A105-2	488			#404		543	
A101-4	553			#405		696	
A101-8	603			ASPEN LAB SHAVINGS		<1	
A103-8	312			BASAL CHOW		<1	
A105-8	242			di WATER Rm. 211		<1	
A103-12	322			NITRIC ACID		<1	
A103-12	598			Pb ACETATE DOS. SOLN		19.12%	
A103-24	376						
A103-72	156			Pb SOIL 9-3		4690	5235
A103-120	80					5159	5093
A102-144	73					4868	
				Pb SOIL 10-1		1590	2092
B202-0.5	<5					1869	2012
B202-1	<5					2005	
B202-2	697			Pb SOIL 3-3		1876	2224
B205-2	296					1787	1933
B201-24	<5					1668	
B203-96	74						

Lead Analysis Report #2: Soils PLW and EC1

Analysis of Pb in Blood, Soil, and Associated Materials
in Support of Haskell Lab Medical Research Project No. MR 9740-001

Author
Keith A. McCleary

Study Completed:
1/26/94

Performed By:
DuPont Specialty Chemicals
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Date 8/10/94