

**BIOAVAILABILITY OF LEAD IN SOIL SAMPLES
FROM THE SMUGGLER MOUNTAIN NPL SITE
ASPEN, COLORADO**

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EXECUTIVE SUMMARY

A study using young swine as test animals was performed to measure the gastrointestinal absorption of lead from two soil samples from the Smuggler Mountain Superfund site in Aspen, Colorado. Young swine were selected for use in the study primarily because the gastrointestinal physiology and overall size of young swine are similar to that of young children, who are the population of prime concern for exposure to soil lead.

The two test soils were composites from different areas of the site. The first sample contained 14,200 ppm lead, and was referred to as the "Berm" sample. The second sample contained 3,870 ppm lead, and was referred to as the "Residential Composite" sample. Groups of 5 swine were given average oral doses of 5.28, 15.9, or 47.5 mg/kg-d of Berm soil or 19.4, 58.1, or 174 mg/kg-d of Residential Composite soil for 15 days. This corresponded to target average doses of 75, 225, or 675 ug/kg/day of lead. Other groups of animals were given a standard lead reference material (lead acetate) either orally at doses of 0, 75 or 225 ug Pb/kg-day, or intravenously at a dose of 100 ug Pb/kg-day. The amount of lead absorbed by each animal was evaluated by measuring the amount of lead in the blood (measured on days -4, 0, 1, 2, 3, 5, 7, 9, 12, and 15), and the amount of lead in liver, kidney and bone (measured on day 15 at study termination). The amount of lead present in blood or tissues of animals exposed to test soils was compared to that for animals exposed to lead acetate, and the results were expressed as relative bioavailability (RBA). For example, a relative bioavailability of 50% means that 50% of the lead in soil was absorbed equally as well as lead from lead acetate, and 50% behaved as if it were not available for absorption. Thus, if lead acetate were 40% absorbed, the test material would be 20% absorbed.

The RBA results for the two samples from the Smuggler Mountain site are summarized below:

Measurement Endpoint	Test Material	
	Berm	Residential
Blood Lead AUC	0.56	0.58
Liver Lead	0.86	0.74
Kidney Lead	0.68	0.74
Bone Lead	0.72	0.68

Because the estimates of RBA based on blood, liver, kidney, and bone do not agree in all cases, judgment must be used in interpreting the data. In general, we recommend greatest emphasis be placed on the RBA estimates derived from the blood lead data. This is because blood lead data are more robust and less susceptible to random errors than the tissue lead data, so there is greater confidence in RBA estimates based on blood lead. In addition, absorption into the central compartment is an early indicator of lead exposure, is the most

relevant index of central nervous system exposure, and is the standard measurement endpoint in investigations of this sort. However, data from the tissue endpoints (liver, kidney, bone) also provide valuable information. We consider the plausible range to extend from the RBA based on blood AUC to the mean of the other three tissues (liver, kidney, bone). The preferred range is the interval from the RBA based on blood to the mean of the blood RBA and the tissue mean RBA. Our suggested point estimate is the mid-point of the preferred range. These values are presented below:

Relative Bioavailability of Lead	Test Material	
	Berm	Residential
Plausible Range	0.56-0.75	0.58-0.72
Preferred Range	0.56-0.65	0.58-0.65
Suggested Point Estimate	0.60	0.61

These RBA estimates may be used to help assess lead risk at this site by refining the estimate of absolute bioavailability (ABA) of lead in soil, as follows:

$$ABA_{\text{soil}} = ABA_{\text{soluble}} \cdot RBA_{\text{soil}}$$

Available data indicate that fully soluble forms of lead are about 50% absorbed by a child. Thus, the estimated absolute bioavailability of lead in the HL Smelter, LL Yard, and HL Mill soils are as follows:

Absolute Bioavailability of Lead	Test Material	
	Berm	Residential
Plausible Range	28%-38%	29%-36%
Preferred Range	28%-33%	29%-32%
Suggested Point Estimate	30%	31%

These absolute bioavailability estimates are appropriate for use in EPA's IEUBK model for this site, although it is clear that there is both natural variability and uncertainty associated with these estimates. This variability and uncertainty arises from several sources, including : 1) the inherent variability in the responses of different individual animals to lead exposure, 2) uncertainty in the relative accuracy and applicability of the different measurement endpoints, 3) the extrapolation of measured RBA values in swine to young children, and 4) the potential effect of food in the stomach on lead absorption. Thus, the values reported above are judged to be reasonable estimates of typical lead absorption by children at this site, but should be interpreted with the understanding that the values are not certain.

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1.0 INTRODUCTION

Absolute and Relative Bioavailability

Bioavailability is a concept that relates to the absorption of chemicals and how absorption depends upon the physical-chemical properties of the chemical and its medium (e.g., dust, soil, rock, food, water, etc.) and the physiology of the exposed receptor. Bioavailability is normally described as the fraction (or percentage) of a chemical which enters into the blood following an exposure of some specified amount, duration and route (usually oral). In some cases, bioavailability may be measured using chemical levels in peripheral tissues such as liver, kidney, and bone, rather than blood. The fraction or percentage absorbed may be expressed either in absolute terms (absolute bioavailability, ABA) or in relative terms (relative bioavailability, RBA). **Absolute bioavailability** is measured by comparing the amount of chemical entering the blood (or other tissue) following oral exposure to test material with the amount entering the blood (or other tissue) following intravenous exposure to an equal amount of some dissolved form of the chemical. Similarly, **relative bioavailability** is measured by comparing oral absorption of test material to oral absorption of some fully soluble form of the chemical (e.g., either the chemical dissolved in water, or a solid form that is expected to fully dissolve in the stomach). For example, if 100 ug of dissolved lead were administered in drinking water and a total of 50 ug entered the blood, the ABA would be 0.50 (50%). Likewise, if 100 ug of lead in soil were administered and 30 ug entered the blood, the ABA for soil would be 0.30 (30%). If the lead dissolved in water were used as the reference substance for describing the relative amount of lead absorbed from soil, the RBA would be $0.30/0.50 = 0.60$ (60%). These values (50% absolute bioavailability of dissolved lead and 30% absolute absorption of lead in soil) are the values currently employed as defaults in EPA's IEUBK model.

It is important to recognize that simple solubility of a test material in water or some other fluid (e.g., a weak acid intended to mimic the gastric contents of a child) may not be a reliable estimator of bioavailability due to the non-equilibrium nature of the dissolution and transport processes that occur in the gastrointestinal tract (Mushak 1991). For example, transport of lead across the gut may continuously shift the equilibrium of a poorly soluble lead compound in the direction of dissolution. However, information on the solubility of lead in different materials is useful in interpreting the importance of solubility as a determinant of bioavailability. To avoid confusion, the term "bioaccessability" is used to refer to the relative amount of lead that dissolves under a specified set of test conditions.

For additional discussion about the concept and application of bioavailability see Goodman et al. (1990), Klaassen et al. (1996), and/or Gibaldi and Perrier (1982).

Using Bioavailability Data to Improve Exposure Calculations for Lead

Data on bioavailability are important for evaluating exposure and potential health effects for a variety of different types of chemicals. This investigation focused mainly on evaluating the bioavailability of lead in various samples of soil or other solid materials from mining, milling or smelting sites. This is because lead may exist, at least in part, as poorly water soluble minerals (e.g., galena), and may also exist inside particles of inert matrix such as rock or slag of variable size, shape and association. These chemical and physical properties may tend to influence (usually decrease) the solubility (bioaccessability) and the absorption (bioavailability) of lead when ingested.

When data are available on the bioavailability of lead in soil, dust, or other soil-like waste material at a site, this information can often be used to improve the accuracy of exposure and risk calculations at that site. The basic equation for estimating the site-specific RBA of a test soil is as follows:

$$ABA_{\text{soil}} = ABA_{\text{soluble}} \cdot RBA_{\text{soil}}$$

where:

$$\begin{aligned} ABA_{\text{soil}} &= \text{Absolute bioavailability of lead in soil ingested by a child} \\ ABA_{\text{soluble}} &= \text{Absolute bioavailability in children of some dissolved or fully soluble form of lead} \\ RBA_{\text{soil}} &= \text{RBA for soil measured in swine} \end{aligned}$$

Based on available information on lead absorption in humans and animals, the EPA estimates that the absolute bioavailability of lead from water and other fully soluble forms of lead is usually about 50% in children. Thus, when a reliable site-specific RBA value for soil is available, it may be used to estimate a site-specific absolute bioavailability as follows:

$$ABA_{\text{soil}} = 50\% \cdot RBA_{\text{soil}}$$

In the absence of site-specific data, the absolute absorption of lead from soil, dust and other similar media is estimated by EPA to be about 30%. Thus, the default RBA used by EPA for lead in soil and dust compared to lead in water is $30\%/50\% = 60\%$. When the measured RBA in soil or dust at a site is found to be less than 60% compared to some fully soluble form of lead, it may be concluded that exposures to and risks from lead in these media at that site are probably lower than typical default assumptions. If the measured RBA is higher than 60%, absorption of and risk from lead in these media may be higher than usually assumed.

2.0 STUDY DESIGN

A standardized study protocol for measuring absolute and relative bioavailability of lead was developed based upon previous study designs and investigations that characterized the young pig model (Weis et al. 1995). The study was performed as nearly as possible within the spirit and guidelines of Good Laboratory Practices (GLP: 40 CFR 792). Standard Operating Procedures (SOPs) that included detailed methods for all aspects of the study were prepared, approved, and distributed to all study members prior to the study. The generalized study design, quality assurance project plan and all standard operating procedures are documented in a project notebook that is available through the administrative record.

2.1 Test Materials

Two samples of soil from the Smuggler Mountain NPL site were tested in this study. The first soil was a composite of nine individual sampling locations collected from the Racquet Club property including the "berm", parking lot, and vacant lot between the tennis court and Park Circle. This is referred to as the "Berm" sample. The second sample was a composite of nine individual sampling locations at residential properties within the study area. This is referred to as the "residential" sample. These samples were selected for study by the EPA Remedial Project Manager and EPA toxicologist for the site, and acknowledged as acceptable by an official from the Pitkin County Health Department. Both samples were dried and sieved, and only the fine fraction (particles less than about 250 μm in diameter) derived from each sample were evaluated. This is because it is believed that soil particles less than about 250 μm are most likely to adhere to the hands and be ingested by hand-to-mouth contact, especially in young children.

Table 2-1 lists the metal content of these samples measured using standard EPA Contract Laboratory program (CLP) methods.

Each soil was well mixed and samples were analyzed by electron microprobe in order to identify a) how frequently particles of various lead minerals were observed, b) how frequently different types of mineral particles occur entirely inside particles of rock or slag ("included") and how often they occur partially or entirely outside rock or slag particles ("liberated"), c) the size distribution of particles of each mineral class, and d) approximately how much of the total amount of lead in the sample occurs in each mineral type. This is referred to as "relative lead mass". The results are summarized in Figure 2-1 and in Table 2-2.

As seen in Figure 2-1, the most common lead-bearing particle types (i.e, those which are observed most often) in both soils are iron-lead oxide, cerussite (lead carbonate), and iron-lead sulfate. Of the relative lead mass in the sample, most occurs in the form of cerussite, with the remainder being composed mostly of galena (lead sulfide) and iron-lead oxide.

TABLE 2-1 METAL ANALYSIS OF TEST MATERIALS

Chemical	Concentration (ppm)	
	Berm Soil	Residential Composite
Aluminum	5,070	8,440
Antimony	5.2	11.4
Arsenic	66.9	16.7
Barium	1,640	1,030
Beryllium	1.3	0.82
Cadmium	41.9	47.4
Calcium	37,200	17,300
Chromium	7.7	10.4
Cobalt	17.1	11.1
Copper	145	51.6
Iron	33,700	23,000
Lead	14,200	3,870
Magnesium	14,300	6,890
Manganese	2,200	934
Mercury	0.77	0.23
Nickel	29.8	21.9
Potassium	1,090	2,140
Selenium	2.0	0.38
Silver	92.3	18.9
Sodium	249	114
Thallium	1.8	0.27
Vanadium	11.5	16.0
Zinc	6,580	4,110

FIGURE 2-1 LEAD MINERALS OBSERVED IN SITE SOILS

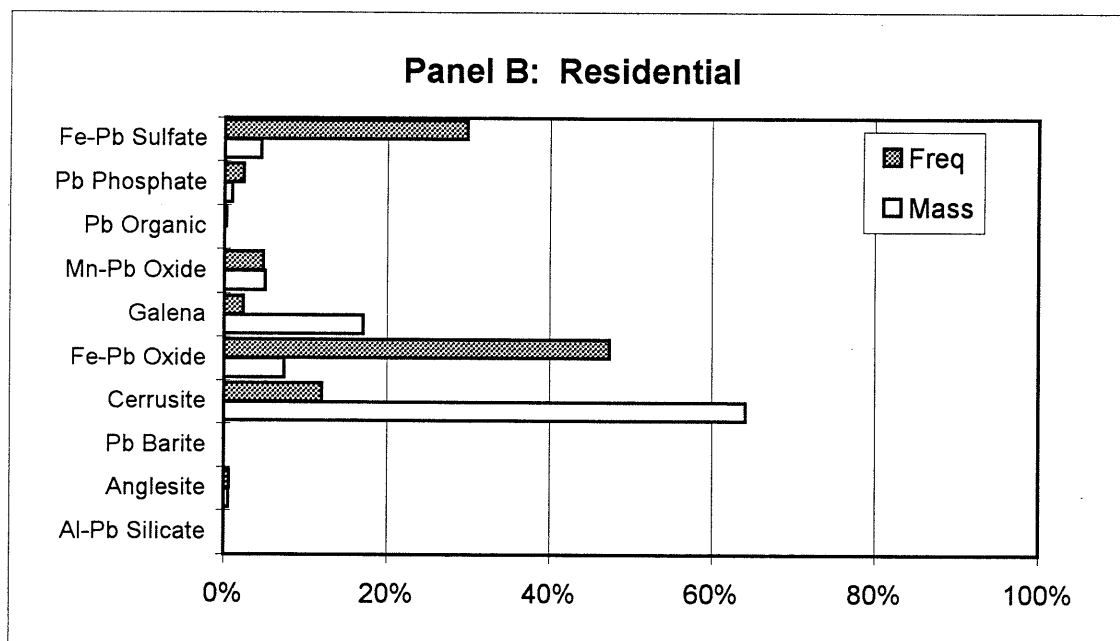
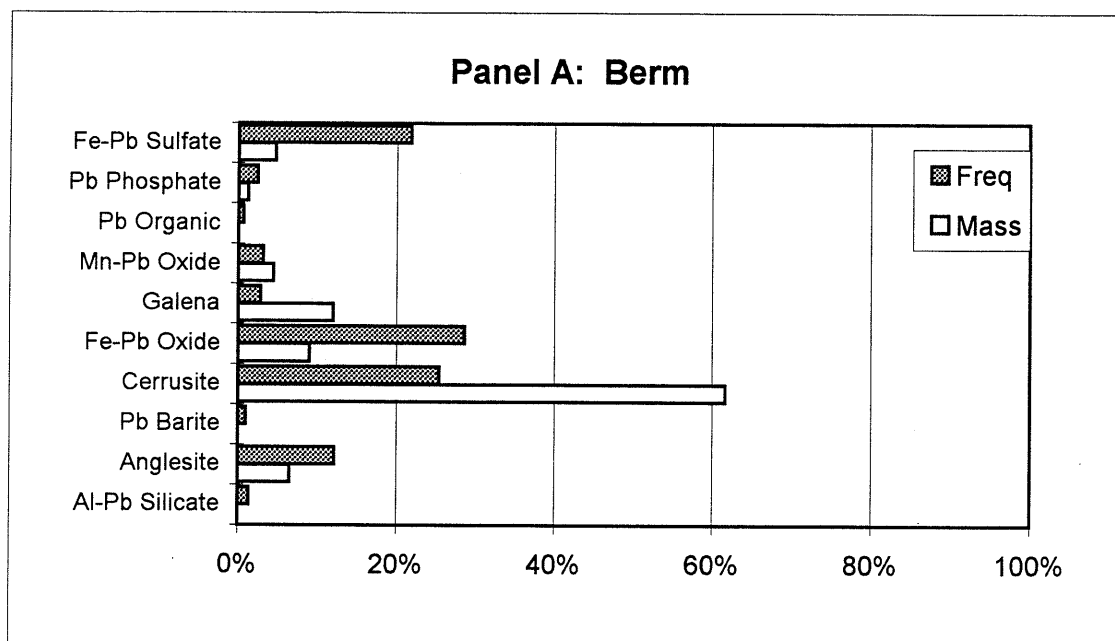


TABLE 2-2 GEOCHEMICAL CHARACTERISTICS OF TEST MATERIALS^a

Mineral Form	Berm						Residential					
	Particle Freq. (%)		Particle Size ^d (um)			Relative Lead Mass ^e (%)	Particle Freq. (%)		Particle size (um)			Relative Lead Mass (%)
	Count-Based ^b	Length-Weighted ^c	min	max	mean		Count-Based	Length-Weighted	min	max	mean	
Pb Silicate	1.4%	3.3%	10	120	55	0.1%	--	--	--	--	--	--
Anglesite	12.2%	2.6%	1	90	5	6.6%	0.7%	0.3%	4	5	5	0.6%
Pb Barite	1.1%	0.45%	2	25	10	0.1%	--	--	--	--	--	--
Cerrusite	25.4%	20.8%	1	110	20	61.7%	12.0%	24.6%	2	125	23	64.2%
Fe-Pb Oxide	28.7%	41.4%	2	210	35	9.1%	47.4%	38.2%	1	100	9	7.4%
Galena	2.9%	3.2%	10	50	27	12.0%	2.4%	5.2%	5	110	25	17.1%
Mn-Pb Oxide	3.2%	7.6%	10	150	56	4.5%	4.8%	9.7%	5	80	23	5.1%
Pb Organic	0.7%	2.1%	40	100	70	0.0003%	0.3%	2.4%	80	80	80	0.00003%
Pb Phosphate	2.5%	4.7%	10	110	45	1.3%	2.4%	4.5%	3	60	21	1.1%
Fe-Pb Sulfate	21.9%	13.8%	4	90	15	4.7%	29.9%	15.2%	1	60	6	4.6%

^a Samples were analyzed using an electron microprobe (JEOL 8600) to identify the number of particles of each lead species present in each sample and the particle size (largest dimension) of each particle.

^b Percentage of all lead-bearing particles of the mineral form shown

^c Percentage of total length of all lead particles consisting of mineral form shown

^d Based on longest dimension of each particle

^e Rough estimate of the percent of the total mass of lead present in each mineral form

FIGURE 2-2 PARTICLE SIZE DISTRIBUTION

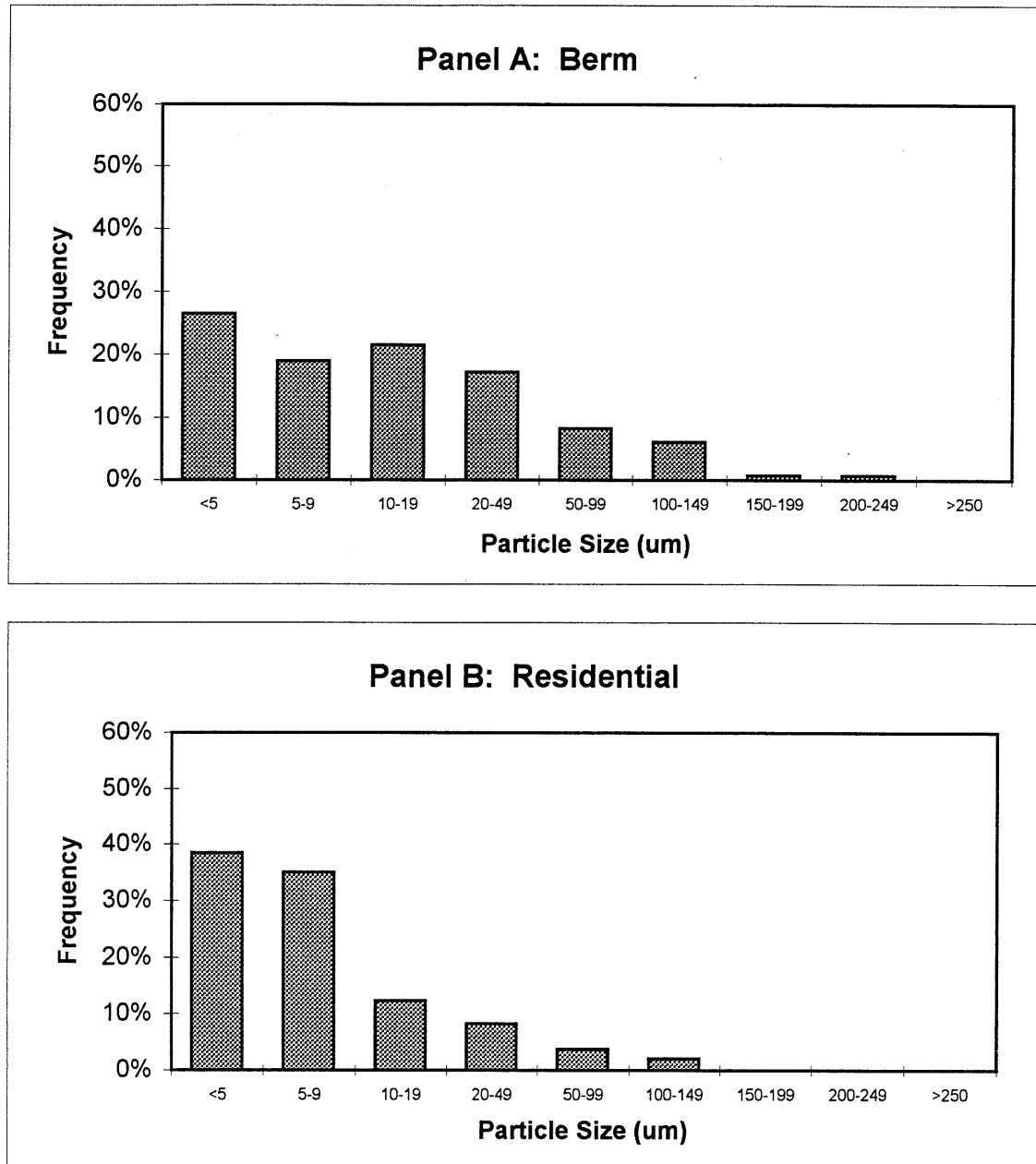
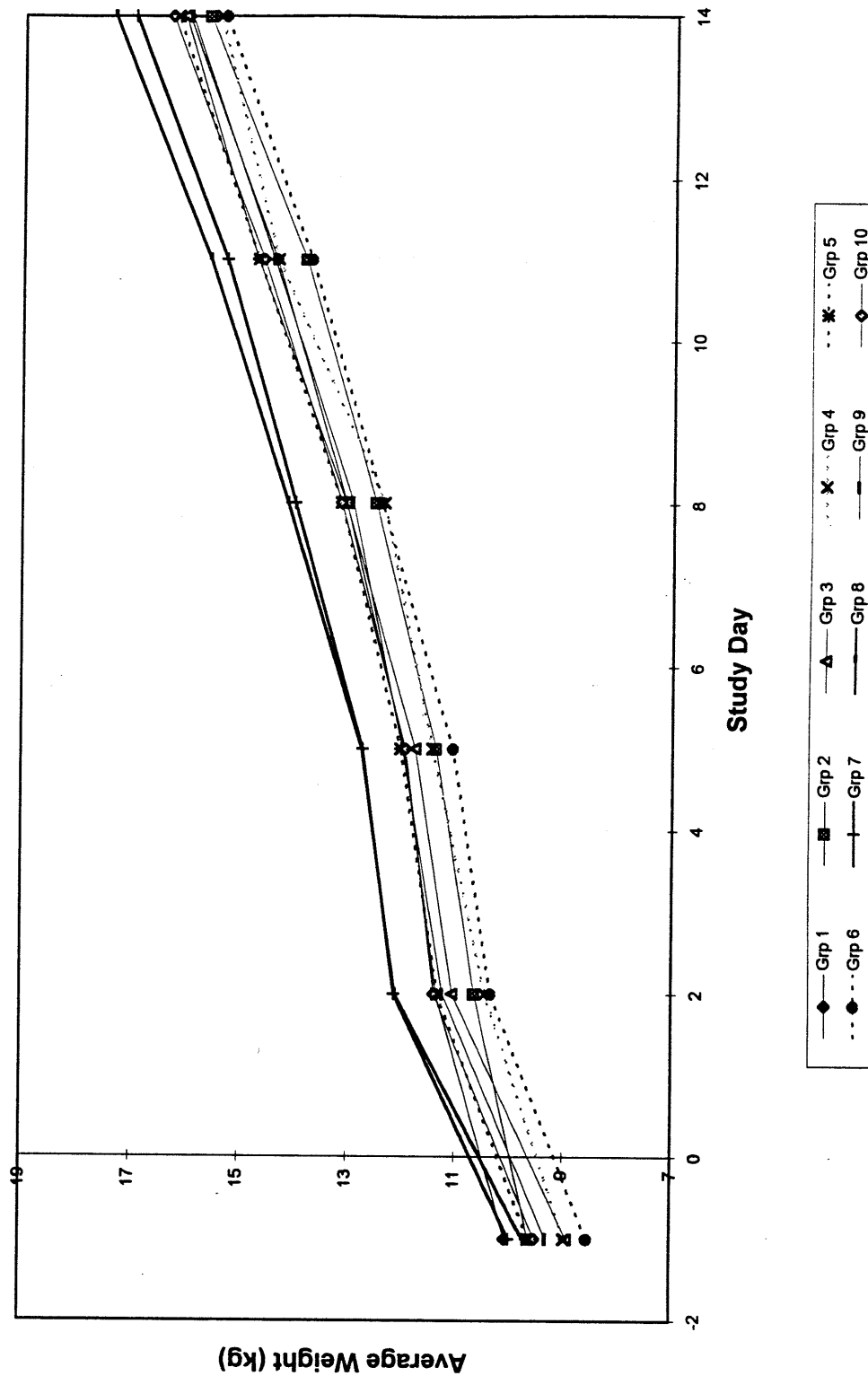


FIGURE 2-3 BODY WEIGHTS OF TEST ANIMALS



2.3 Diet

Animals provided by the supplier were weaned onto standard pig chow purchased from MFA Inc., Columbia, MO. In order to minimize lead exposure from the diet, the animals were gradually transitioned from the MFA feed to a special low-lead feed (guaranteed less than 0.2 ppm lead, purchased from Zeigler Brothers, Inc., Gardners, PA) over the time interval from day -7 to day -3, and this feed was then maintained for the duration of the study. The feed was nutritionally complete and met all requirements of the National Institutes of Health-National Research Council. The typical nutritional components and chemical analysis of the feed is presented in Table 2-3. Typically, the feed contained approximately 5.7% moisture, 1.7% fiber, and provided about 3.4 kcal of metabolizable energy per gram. Periodic analysis of feed samples during this program indicated the mean lead level (treating non-detects at one-half the quantitation limit of 0.05 ppm) was less than 0.05 ppm.

Each day every animal was given an amount of feed equal to 5% of the mean body weight of all animals on study. Feed was administered in two equal portions of 2.5% of the mean body weight at each feeding. Feed was provided at 11:00 AM and 5:00 PM daily. Drinking water was provided ad libitum via self-activated watering nozzles within each cage. Periodic analysis of samples from randomly selected drinking water nozzles indicated the mean lead concentration (treating non-detects at one-half the quantitation limit) was less than 2 ug/L.

2.4 Dosing

The protocol for exposing animals to lead is shown in Table 2-4. Animals were exposed to lead for 15 days, with the dose for each day being administered in two equal portions given at 9:00 AM and 3:00 PM (two hours before feeding). Doses were based on measured group mean body weights, and were adjusted every three days to account for animal growth. For animals exposed by the oral route, dose material was placed in the center of a small portion (about 5 grams) of moistened feed, and this was administered to the animals by hand. Most animals consumed the dose promptly, but occasionally some animals delayed ingestion of the dose for up to two hours (the time the daily feed portion was provided). These delays are noted in the data provided in Appendix A, but are not considered to be a significant source of error. Occasionally, some animals did not consume some or all of the dose (usually because the dose dropped from their mouth while chewing). All missed doses were recorded and the time-weighted average dose calculation for each animal was adjusted downward accordingly. Any animal that missed 5 or more of the 30 total oral doses administered during the study was excluded from data analysis. There were no animals that missed doses in this study.

For animals exposed by intravenous injection, doses were given via a vascular access port (VAP) attached to an indwelling venous catheter that had been surgically implanted according to standard operating procedures by a board-certified veterinary surgeon through the external jugular vein to the cranial vena cava about 3 to 5 days before exposure began.

TABLE 2-3 TYPICAL FEED COMPOSITION^a

Nutrient Name	Amount	Nutrient Name	Amount
Protein	20.1021 %	Chlorine	0.1911 %
Arginine	1.2070 %	Magnesium	0.0533 %
Lysine	1.4690 %	Sulfur	0.0339 %
Methionine	0.8370 %	Manganese	20.4719 ppm
Met+Cys	0.5876 %	Zinc	118.0608 ppm
Tryptophan	0.2770 %	Iron	135.3710 ppm
Histidine	0.5580 %	Copper	8.1062 ppm
Leucine	1.8160 %	Cobalt	0.0110 ppm
Isoleucine	1.1310 %	Iodine	0.2075 ppm
Phenylalanine	1.1050 %	Selenium	0.3196 ppm
Phe+Tyr	2.0500 %	Nitrogen Free Extract	60.2340 %
Threonine	0.8200 %	Vitamin A	5.1892 kIU/kg
Valine	1.1910 %	Vitamin D3	0.6486 kIU/kg
Fat	4.4440 %	Vitamin E	87.2080 IU/kg
Saturated Fat	0.5590 %	Vitamin K	0.9089 ppm
Unsaturated Fat	3.7410 %	Thiamine	9.1681 ppm
Linoleic 18:2:6	1.9350 %	Riboflavin	10.2290 ppm
Linoleic 18:3:3	0.0430 %	Niacin	30.1147 ppm
Crude Fiber	3.8035 %	Pantothenic Acid	19.1250 ppm
Ash	4.3347 %	Choline	1019.8600 ppm
Calcium	0.8675 %	Pyridoxine	8.2302 ppm
Phos Total	0.7736 %	Folacin	2.0476 ppm
Available Phosphorous	0.7005 %	Biotin	0.2038 ppm
Sodium	0.2448 %	Vitamin B12	23.4416 ppm
Potassium	0.3733 %		

^a Nutritional values provided by Zeigler Bros., Inc.

TABLE 2-4 DOSING PROTOCOL

Group	Number of Animals	Dose Material Administered	Exposure Route	Lead Dose (ug Pb/kg-d)	
				Target	Actual ^a
1	2	None	Oral	0	0
2	5	Lead acetate	Oral	75	77
3	5	Lead acetate	Oral	225	224
4	5	Berm soil	Oral	75	76
5	5	Berm soil	Oral	225	229
6	5	Berm soil	Oral	675	732
7	5	Residential soil	Oral	75	71
8	5	Residential soil	Oral	225	227
9	5	Residential soil	Oral	675	685
10	8	Lead acetate	Intravenous	100	102

Doses were administered in two equal portions given at 9:00 AM and 3:00 PM each day. Doses were based on the mean weight of the animals in each group, and were adjusted every three days to account for weight gain.

^a Calculated as the administered daily dose divided by the measured or extrapolated daily body weight, averaged over days 0-14 for each animal and each group.

Actual mean doses, calculated from the administered doses and the measured body weights, are also shown in Table 2-4.

2.5 Collection of Biological Samples

Blood

Samples of blood were collected from each animal four days before exposure began (day -4), on the first day of exposure (day 0), and on days 1, 2, 3, 5, 7, 9, 12, and 15 following the start of exposure. All blood samples were collected by vena-puncture of the anterior vena cava, and samples were immediately placed in purple-top Vacutainer® tubes containing EDTA as anticoagulant. Blood samples were collected each sampling day beginning at 8:00 AM, approximately one hour before the first of the two daily exposures to lead on the sampling day and 17 hours after the last lead exposure the previous day. This blood collection time was selected because the rate of change in blood lead resulting from the preceding exposures is expected to be relatively small after this interval (LaVelle et al. 1991, Weis et al. 1993), so the exact timing of sample collection relative to last dosing is not likely to be critical.

Following collection of the final blood sample at 8:00 AM on day 15, all animals were humanely euthanized and samples of liver, kidney and bone (the right femur) were removed and stored in lead-free plastic bags for lead analysis. Samples of all biological samples collected were archived in order to allow for later reanalysis and verification, if needed. All animals were also subjected to detailed examination at necropsy by a certified veterinary pathologist in order to assess overall animal health.

2.6 Preparation of Biological Samples for Analysis

Blood

One mL of whole blood was removed from the purple-top Vacutainer and added to 9.0 mL of "matrix modifier", a solution recommended by the Centers for Disease Control and Prevention (CDCP) for analysis of blood samples for lead. The composition of matrix modifier is 0.2% (v/v) ultrapure nitric acid, 0.5% (v/v) Triton X-100, and 0.2% (w/v) dibasic ammonium phosphate in deionized and ultrafiltered water. Samples of the matrix modifier were routinely analyzed for lead to ensure the absence of lead contamination.

Liver and Kidney

One gram of soft tissue (liver or kidney) was placed in a lead-free screw-cap teflon container with 2 mL of concentrated (70%) nitric acid and heated in an oven to 90°C overnight. After cooling, the digestate was transferred to a clean lead-free 10 mL volumetric flask and diluted to volume with deionized and ultrafiltered water.

Bone

The right femur of each animal was removed and defleshed, and dried at 100°C overnight. The dried bones were then placed in a muffle furnace and dry-ashed at 450°C for 48 hours. Following dry ashing, the bone was ground to a fine powder using a lead-free mortar and pestle, and 200 mg was removed and dissolved in 10.0 mL of 1:1 (v:v) concentrated nitric acid:water. After the powdered bone was dissolved and mixed, 1.0 mL of the acid solution was removed and diluted to 10.0 mL by addition of 0.1% (m/v) lanthanum oxide (La_2O_3) in deionized and ultrafiltered water.

2.7 Lead Analysis

Samples of biological tissue (blood, liver, kidney, bone) and other materials (food, water, reagents and solutions, etc.) were arranged in a random sequence and provided to EPA's analytical laboratory in a blind fashion (identified to the laboratory only by a chain of custody tag number). Each sample was analyzed for lead using a Perkin Elmer Model 5100 graphite furnace atomic absorption spectrophotometer. Internal quality assurance samples were run every tenth sample, and the instrument was recalibrated every 15th sample. A blank, duplicate and spiked sample were run every 20th sample.

All results from the analytical laboratory were reported in units of ug Pb/L of prepared sample. The quantitation limit was defined as three-times the standard deviation of a set of seven replicates of a low-lead sample (typically about 2-5 ug/L). The standard deviation was usually about 0.3 ug/L, so the quantitation limit was usually about 0.9-1.0 ug/L (ppb). For prepared blood samples (diluted 1/10), this corresponds to a quantitation limit of 10 ug/L (1 ug/dL). For soft tissues (liver and kidney, diluted 1/10), this corresponds to a quantitation limit of 10 ug/kg (ppb) wet weight, and for bone (final dilution = 1/500) the corresponding quantitation limit is 0.5 ug/g (ppm) ashed weight.

3.0 DATA ANALYSIS

3.1 Overview

Studies on the absorption of lead are often complicated because some biological responses to lead exposure may be non-linear functions of dose (i.e., tending to flatten out or plateau as dose increases). The cause of this non-linearity is uncertain but might be due either to non-linear **absorption kinetics** and/or to non-linear **biological response** per unit dose absorbed. When the dose-response curve for either the reference material (lead acetate) and/or the test material is non-linear, RBA is equal to the ratio of doses that produce equal responses (not the ratio of responses at equal doses). This is based on the simple but biologically plausible assumption that equal absorbed doses yield equal biological responses. Applying this assumption leads to the following general methods for calculating RBA from a set of non-linear experimental data:

1. Plot the biological responses for individual animals exposed to a series of oral doses of soluble lead (e.g., lead acetate). Find an equation which gives a smooth best fit line through the observed data.
2. Plot the biological response for individual animals exposed to a series of doses of test material. Find an equation which gives a smooth fit line through the observed data.
3. Using the best fit equations for reference material and test material, calculate RBA as the ratios of doses of test material and reference material which yield equal biological responses. Depending on the relative shape of the best-fit lines through the lead acetate and test material dose response curves, RBA may either be constant (dose-independent) or variable (dose-dependent).

The principal advantage of this approach is that it is not necessary to understand the basis for a non-linear dose response curve (non-linear absorption and/or non-linear biological response) in order to derive valid RBA estimates. Also, it is important to realize that this method is very general, as it will yield correct results even if one or both of the dose-response curves are linear. In the case where both curves are linear, RBA is dose-independent and is simply equal to the ratio of the slopes of the best-fit linear equations.

3.2 Fitting the Curves

There are a number of different mathematical equations which can yield reasonable fits with the dose-response data sets obtained in this study. In selecting which equations to employ, the following principles were applied: 1) mathematically simple equations were preferred over mathematically complex equations, 2) the shape of the curves had to be smooth and biologically realistic, without inflection points, maxima or minima, and 3) the general form of the equations had to be able to fit data not only from this one study, but from all the studies that are part of

this project. After testing a wide variety of different equations, it was found that all data sets could be well fitted using one of the following three forms:

Linear (LIN): Response = $a + b \cdot \text{Dose}$

Exponential (EXP): Response = $a + c \cdot (1 - \exp(-d \cdot \text{Dose}))$

Combination (LIN+EXP): Response = $a + b \cdot \text{Dose} + c \cdot (1 - \exp(-d \cdot \text{Dose}))$

Although underlying mechanism was not considered in selecting these equations, the linear equation allows fitting data that do not show evidence of saturation in either uptake or response, while the exponential and mixed equations allow evaluation of data that appear to reflect some degree of saturation in uptake and/or response.

Each dose-response data set was fit to each of the equations above. If one equation yielded a fit that was clearly superior (as judged by the value of the adjusted correlation coefficient R^2) to the others, that equation was selected. If two or more models fit the data approximately equally well, then the simplest model (that with the fewest parameters) was selected. In the process of finding the best-fits of these equations to the data, the values of the parameters (a, b, c, and d) were subjected to some constraints, and some data points (those that were outside the 95% prediction limits of the fit) were excluded. These constraints and outlier exclusion steps are detailed in Appendix A (Section 3). In general, most blood lead AUC dose-response curves were best fit by the exponential equation, and most dose-response curves for liver, kidney and bone were best fit by linear equations.

3.3 Responses Below Quantitation Limit

In some cases, most or all of the responses in a group of animals were below the quantitation limit for the endpoint being measured. For example, this was normally the case for blood lead values in unexposed animals (both on day -4 and day 0, and in control animals), and also occurred during the early days in the study for animals given test materials with low bioavailability. In these cases, all animals which yielded responses below the quantitation limit were evaluated as if they had responded at one-half the quantitation limit.

3.4 Quality Assurance

A number of steps were taken throughout this study and the other studies in this project to ensure the quality of the results. These steps are summarized below.

Duplicates

A randomly selected set of about 5% of all samples generated during the study were submitted to the laboratory in a blind fashion for duplicate analysis. The raw data are presented in

Appendix A, and Figure 3-1 plots the results for blood (Panel A, upper) and for bone, liver and kidney (Panel B, lower). As seen, there was good intra-laboratory reproducibility between duplicate samples for all tissues, with linear regression lines having a slope near 1.0, an intercept near zero, and an R^2 value near 1.0.

Standards

The Centers for Disease Control and Prevention (CDCP) provides a variety of blood lead "check samples" for use in quality assurance programs for blood lead studies. Each time a group of blood samples was prepared and sent to the laboratory for analysis, several CDCP check samples of different concentrations were included in random order and in a blind fashion.

The results for the samples submitted during this study are presented in Appendix A, and the values are plotted in Figure 3-2 (Panel A, upper). As seen, the analytical results obtained for the check samples tended to be low for both standards employed (nominal concentrations = 1.7 ug/dL and 4.8 ug/dL).

Interlaboratory Comparison

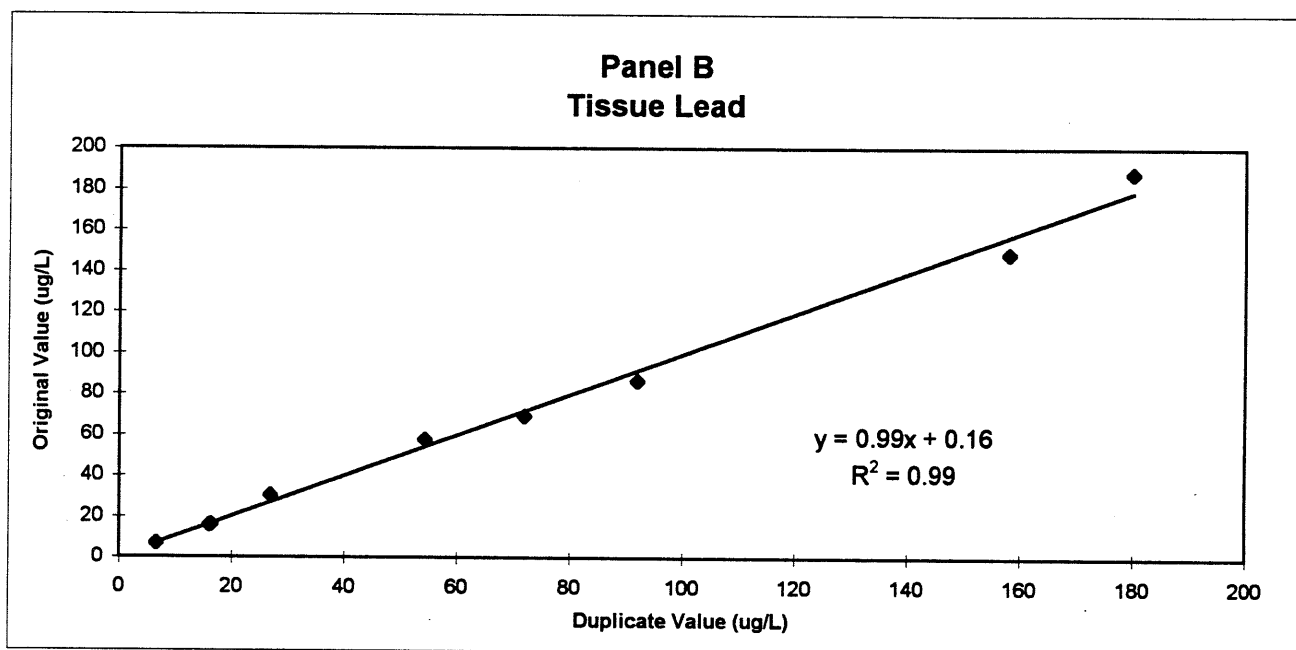
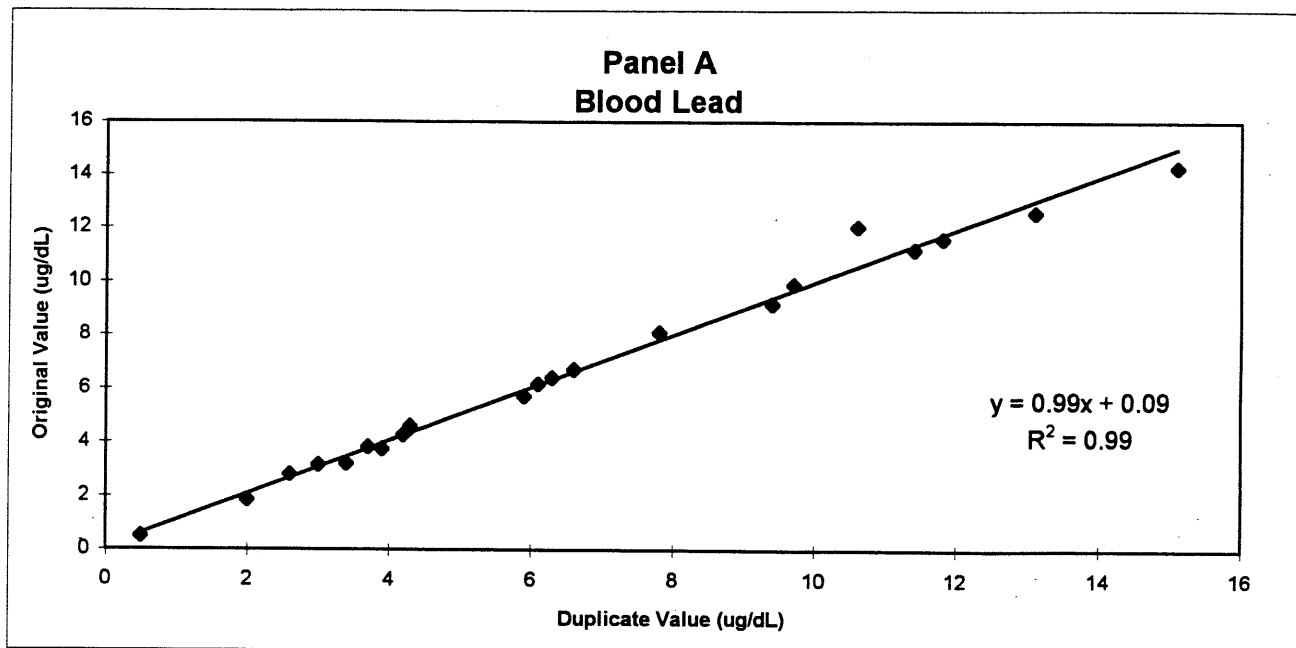
An interlaboratory comparison of blood lead analytical results was performed by sending a set of 15 randomly selected whole blood samples from this study to CDCP for blind independent preparation and analysis. The results are presented in Appendix A, and the values are plotted in Figure 3-2 (Panel B, lower). As seen, the results of analyses by EPA's laboratory tended to be about 20% lower than the values measured by CDCP.

The reason for this apparent discrepancy between the EPA laboratory and the CDCP laboratory is not clear, but might be related to differences in sample preparation techniques. Regardless of the reason, the differences are sufficiently small that they are likely to have no significant effect on calculated RBA values. In particular, it is important to realize that if both the lead acetate and test soils dose-response curves are biased by the same factor, then the biases cancel in the calculation of the ratio.

Data Audits and Spreadsheet Validation

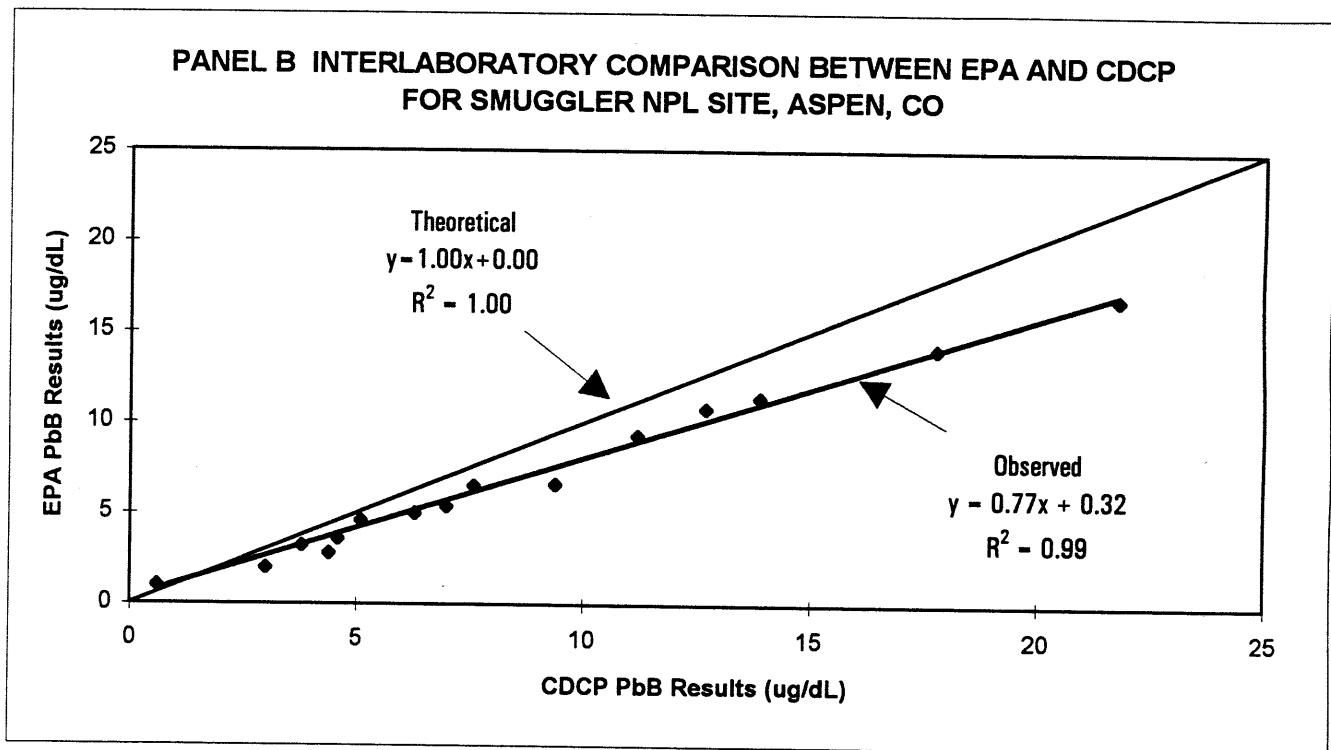
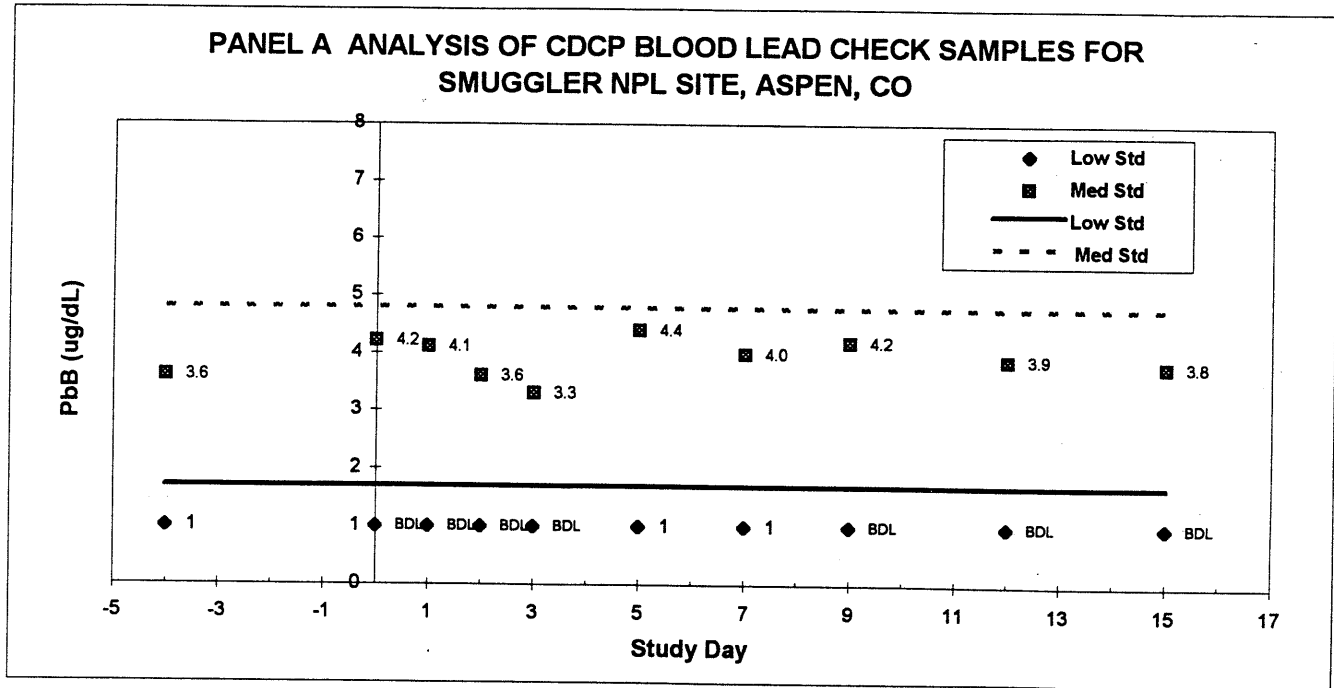
All analytical data generated by EPA's analytical laboratory were validated prior to being released in the form of a database file. These electronic data files were "decoded" (linking the sample tag to the correct animal and day) using Microsoft's database system ACCESS® (Version 5 for Windows). To ensure that no errors occurred in this process, original downloaded electronic files were printed out and compared to printouts of the tag assignments and the decoded data. All spreadsheets used to manipulate the data and to perform calculations (see Appendix A) were validated by hand-checking random cells for accuracy.

**FIGURE 3-1 COMPARISON OF DUPLICATE ANALYSES
SMUGGLER NPL SITE, ASPEN, CO**



Blind random duplicates submitted at a 5% rate to EPA laboratories to provide
a measure of analytical precision (reproducibility)

FIGURE 3-2 CDCP CHECK SAMPLES FOR SMUGGLER NPL SITE, ASPEN, CO



4.0 RESULTS

The following sections provide results based on the group means for each dose group investigated in this study. Appendix A provides detailed data for each individual animal.

4.1 Blood Lead vs Time

Figure 4-1 shows the group mean blood lead values as a function of time during the study. As seen, blood lead values began below quantitation limits (about 1 ug/dL) in all groups, and remained below quantitation limits in control animals (Group 1). In animals given repeated oral doses of lead acetate (Groups 2 and 3), berm soil (Groups 4-6, upper panel), or residential composite soil (Groups 7-9, lower panel), blood levels began to rise within 1-2 days, and tended to plateau by the end of the study (day 15). A similar pattern was observed in animals exposed to lead acetate by intravenous injection (Group 10).

4.2 Dose-Response Patterns

Blood Lead

The measurement endpoint used to quantify the blood lead response was the area under the curve (AUC) for blood lead vs time (days 0-15). This AUC was calculated using the trapezoidal rule to estimate the AUC between each time point that a blood lead value was measured (days 0, 1, 2, 3, 5, 7, 9, 12, and 15), and summing the areas across all time intervals in the study. The detailed data and calculations are presented in Appendix A, and the results are shown graphically in Figure 4-2. Each data point reflects the group mean exposure and group mean response, with the variability in dose and response shown by standard error bars. The figure also shows the best-fit equation through each data set.

As seen, the dose response pattern is non-linear for both the soluble reference material (lead acetate, abbreviated "PbAc"), and for each of the two test soils. The dose response curves for each of the two test materials are quite similar to each other, and both are somewhat lower than the curve for lead acetate.

Tissue Lead

The dose-response data for lead levels in bone, liver and kidney (measured at sacrifice on day 15) are detailed in Appendix A, and are shown graphically in Figures 4-3 through 4-5, respectively. As seen, all of these dose response curves for tissues are fit by linear equations. As was the case for blood lead, the responses of the two test soils tend to be similar to each other. The responses for liver, bone and kidney all appear to be slightly lower than lead acetate.

FIGURE 4-1 GROUP MEAN BLOOD LEAD BY DAY FOR
SMUGGLER NPL SITE, ASPEN, CO

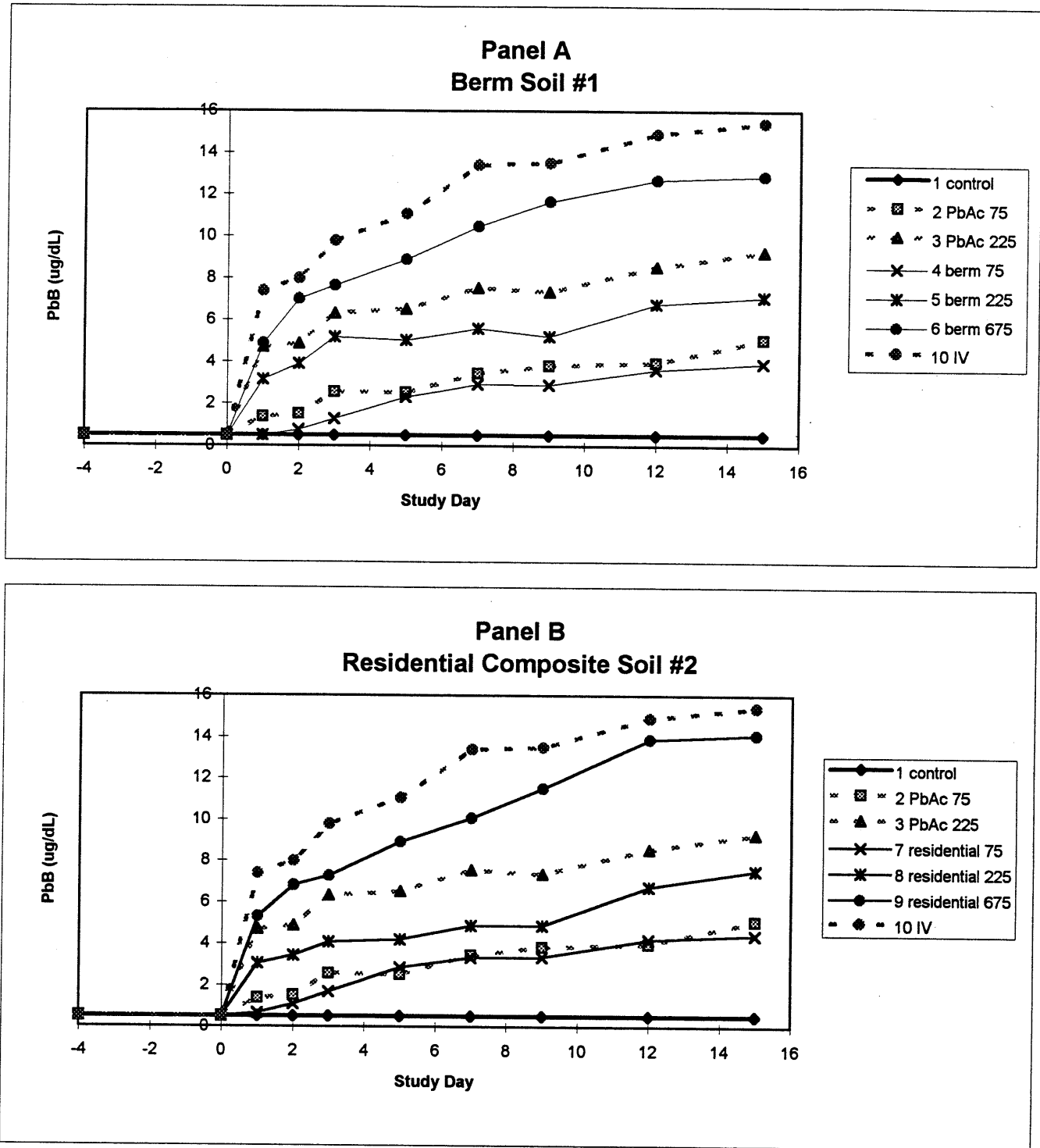


FIGURE 4-2 BLOOD LEAD DOSE-RESPONSE, GROUP MEANS \pm SEM FOR
SMUGGLER NPL SITE, ASPEN, CO

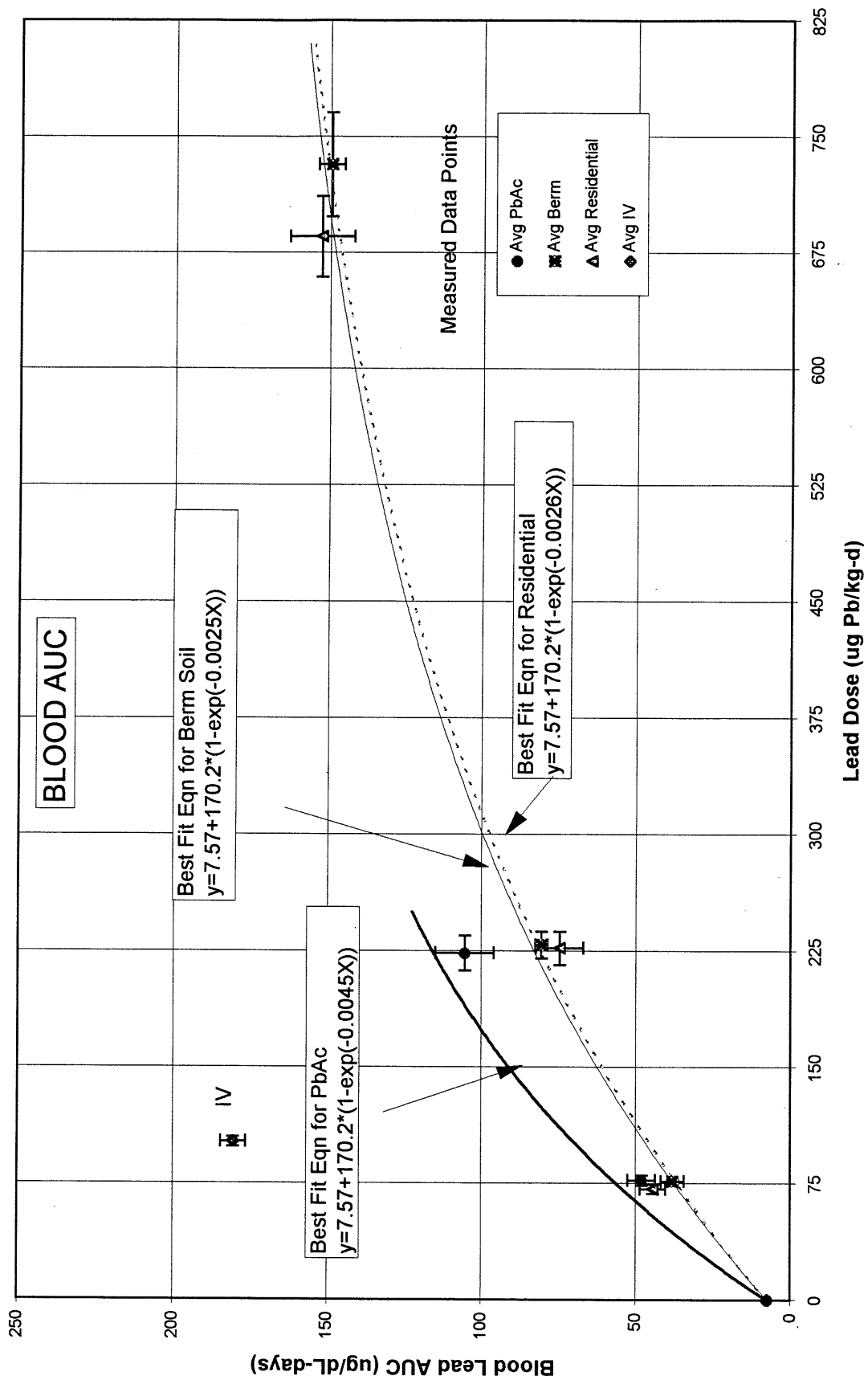


FIGURE 4-3 BONE LEAD DOSE-RESPONSE, GROUP MEANS \pm SEM FOR
SMUGGLER NPL SITE, ASPEN, CO

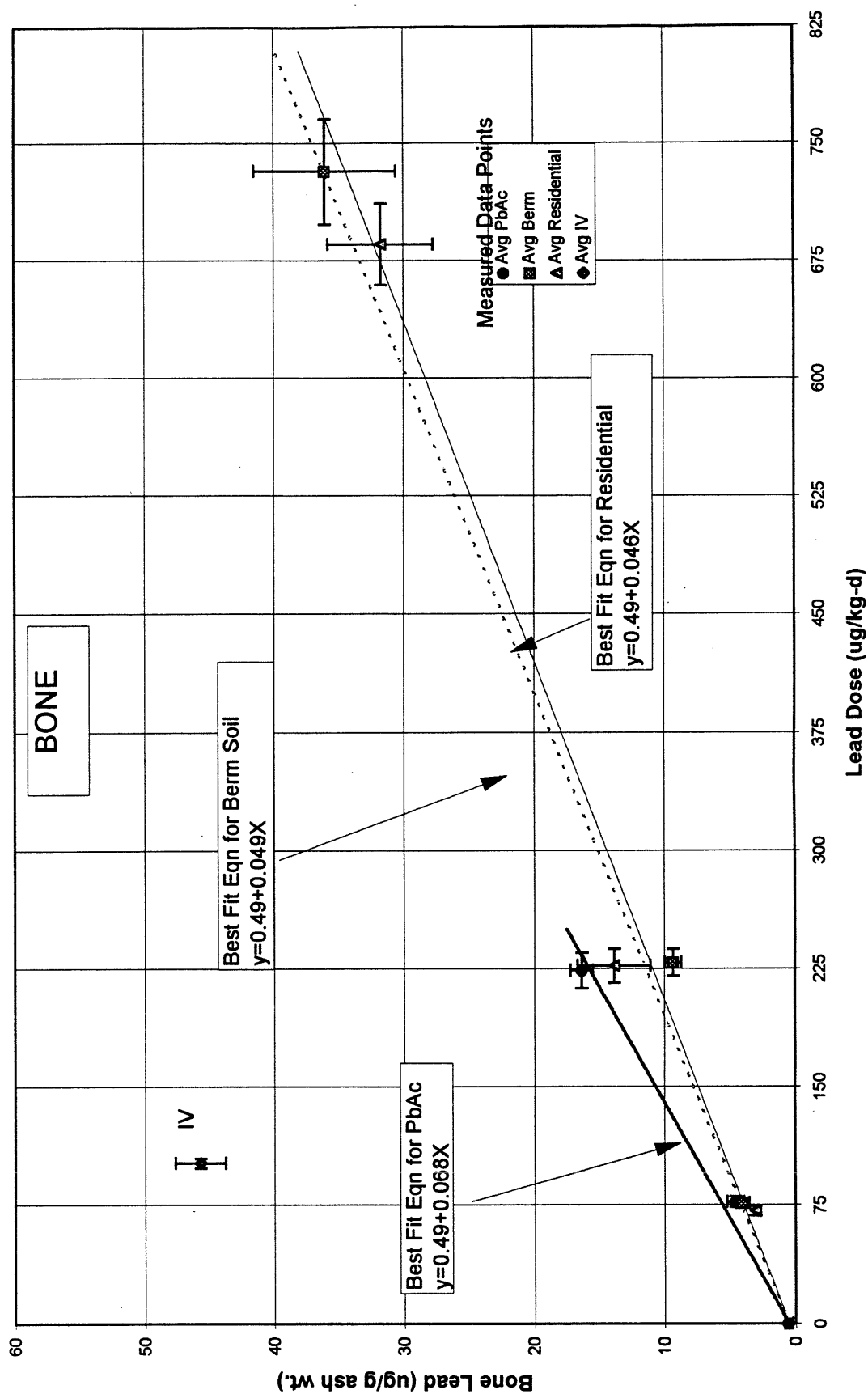


FIGURE 4-4 LIVER LEAD DOSE-RESPONSE, GROUP MEANS \pm SEM FOR
SMUGGLER NPL SITE, ASPEN, CO

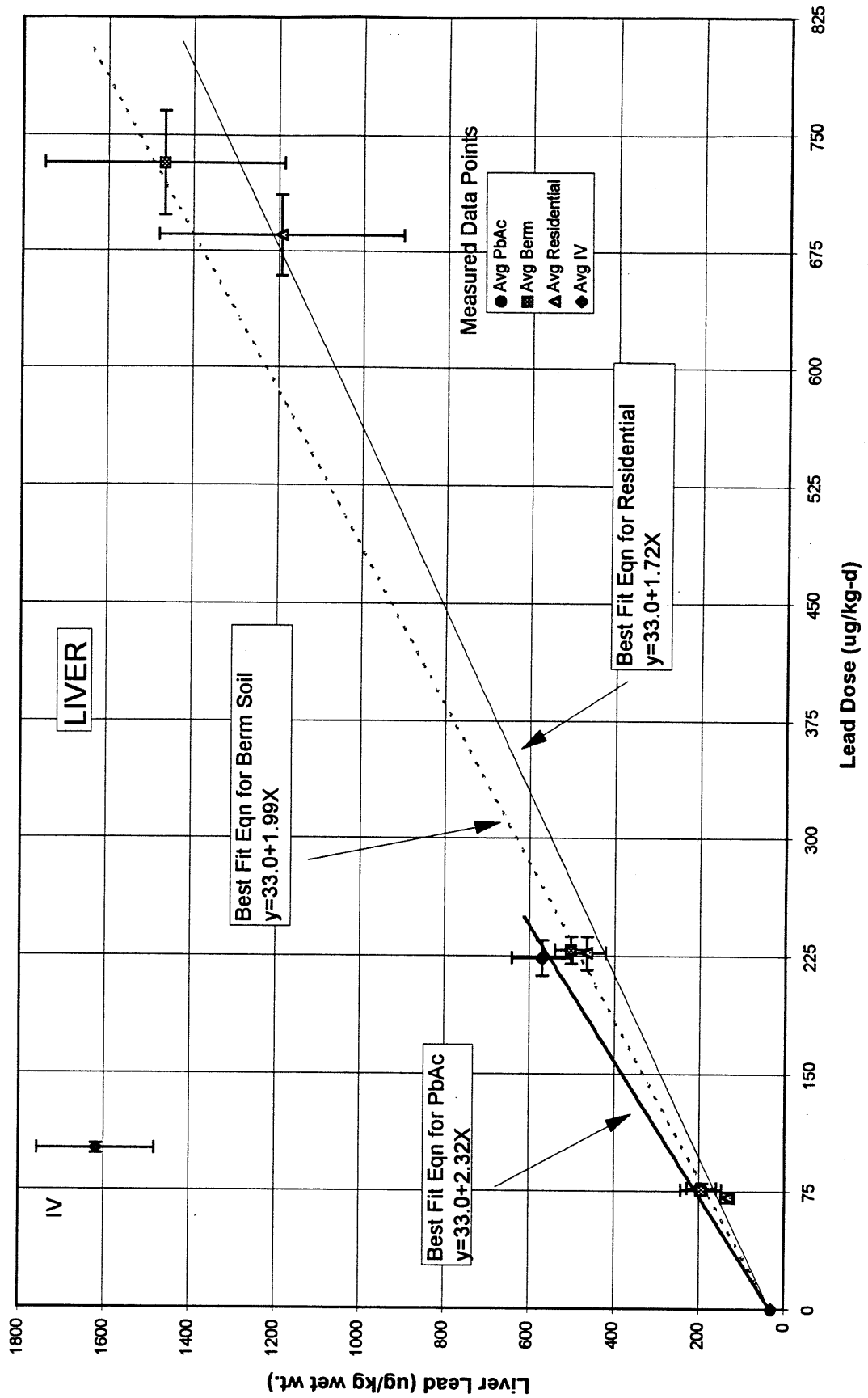
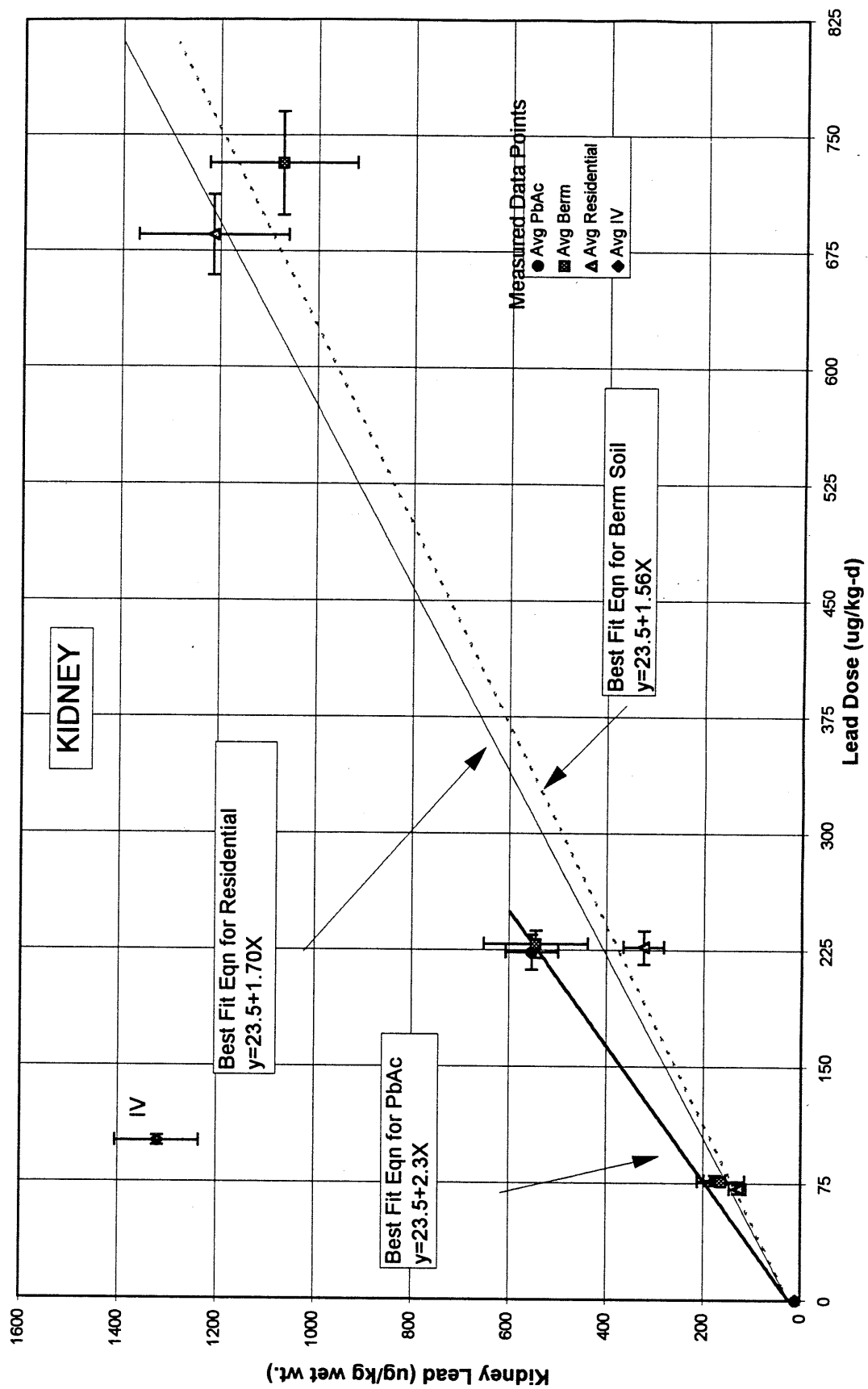


FIGURE 4-5 KIDNEY LEAD DOSE-RESPONSE, GROUP MEANS \pm SEM FOR
SMUGGLER NPL SITE, ASPEN, CO



4.3 Calculated RBA Values

Relative bioavailability values were calculated for each test material for each measurement endpoint (blood, bone, liver, kidney) using the method described in Section 3.0. The results are shown below:

Measurement Endpoint	Test material	
	Berm	Residential
Blood Lead AUC	0.56	0.58
Liver Lead	0.86	0.74
Kidney Lead	0.68	0.74
Bone Lead	0.72	0.68

Recommended RBA Values

As shown above, for each test material, there are four independent estimates of RBA (based on blood, liver, kidney, and bone), and the values do not agree in all cases. In general, we recommend greatest emphasis be placed on the RBA estimates derived from the blood lead data. There are several reasons for this recommendation, including the following:

- 1) Blood lead calculations are based on multiple measurements over time, and so are statistically more robust than the single measurements available for tissue concentrations. Further, blood is a homogeneous medium, and is easier to sample than complex tissues such as liver, kidney and bone. Consequently, the AUC endpoint is less susceptible to random measurement errors, and RBA values calculated from AUC data are less uncertain.
2. Blood is the central compartment and one of the first compartments to be affected by absorbed lead. In contrast, uptake of lead into peripheral compartments (liver, kidney, bone) depend on transfer from blood to the tissue, and may be subject to a variety of toxicokinetic factors that could make bioavailability determinations more complicated.
3. The dose-response curve for blood lead is non-linear, similar to the non-linear dose-response curve observed in children (e.g., see Sherlock and Quinn 1986). Thus, the response of this endpoint is known to behave similarly in swine as in children, and it is not known if the same is true for the tissue endpoints.
4. Blood lead is the classical measurement endpoint for evaluating exposure and health effects in humans, and the health effects of lead are believed to be proportional to blood lead levels.

However, data from the tissue endpoints (liver, kidney, bone) also provide valuable information. We consider the plausible range to extend from the RBA based on blood AUC to the mean of the other three tissues (liver, kidney, bone). The preferred range is the interval from the RBA based on blood to the mean of the blood RBA and the tissue mean RBA. Our suggested point estimate is the mid-point of the preferred range. These values are presented below:

Relative Bioavailability of Lead	Test Material	
	Berm	Residential
Plausible range	0.56-0.75	0.58-0.72
Preferred range	0.56-0.65	0.58-0.65
Suggested Point Estimate	0.60	0.61

4.4 Estimated Absolute Bioavailability in Children

These RBA estimates may be used to help assess lead risk at this site by refining the estimate of absolute bioavailability (ABA) of lead in soil, as follows:

$$ABA_{\text{soil}} = ABA_{\text{soluble}} \cdot RBA_{\text{soil}}$$

Available data indicate that fully soluble forms of lead are about 50% absorbed by a child (USEPA 1991, 1994). Thus, the estimated absolute bioavailability of lead in site soils are calculated as follows:

$$ABA_{\text{Berm}} = 50\% \cdot RBA_{\text{Berm}}$$

$$ABA_{\text{Residential}} = 50\% \cdot RBA_{\text{Residential}}$$

Based on the RBA values shown above, the estimated absolute bioavailabilities in children are as follows:

Absolute Bioavailability of Lead	Test Material	
	Berm	Residential
Plausible range	28%-38%	29%-36%
Preferred range	28%-33%	29%-32%
Suggested Point Estimate	30%	31%

4.5 Uncertainty

These absolute bioavailability estimates are appropriate for use in EPA's IEUBK model for this site, although it is clear that there is both variability and uncertainty associated with these estimates. This variability and uncertainty arises from several sources. First, differences in physiological and pharmacokinetic parameters between individual animals leads to variability in response even when exposure is the same. Because of this inter-animal variability in the responses of different animals to lead exposure, there is mathematical uncertainty in the best fit dose-response curves for both lead acetate and test material. This in turn leads to uncertainty in the calculated values of RBA, because these are derived from the two best-fit equations. Second, there is uncertainty in how to weight the RBA values based on the different endpoints, and how to select a point estimate for RBA that is applicable to typical site-specific exposure levels. Third, there is uncertainty in the extrapolation of measured RBA values in swine to young children. Even though the immature swine is believed to be a useful and meaningful animal model for gastrointestinal absorption in children, it is possible that differences in stomach pH, stomach emptying time, and other physiological parameters may exist and that RBA values in swine may not be precisely equal to values in children. Finally, studies in humans reveal that lead absorption is not constant even within an individual, but varies as a function of many factors (mineral intake, health status, etc.). One factor that may be of special importance is time after the last meal, with the presence of food tending to reduce lead absorption. The values of RBAs measured in this study are intended to estimate the maximum uptake that occurs when lead is ingested in the absence of food. Thus, these values may be somewhat conservative for children who ingest lead along with food. The magnitude of this bias is not known, although preliminary studies in swine suggest the factor may be relatively minor.

5.0 REFERENCES

- Gibaldi, M. and Perrier, D. 1982. *Pharmacokinetics* (2nd edition) pp 294-297. Marcel Dekker, Inc, NY, NY.
- Goodman, A.G., Rall, T.W., Nies, A.S., and Taylor, P. 1990. *The Pharmacological Basis of Therapeutics* (8th ed.) pp. 5-21. Pergamon Press, Inc. Elmsford, NY.
- Klaassen, C.D., Amdur, M.O., and Doull, J. (eds). 1996. *Cassarett and Doull's Toxicology: The Basic Science of Poisons*. pp. 190. McGraw-Hill, Inc. NY,NY
- LaVelle, J.M., Poppenga, R.H., Thacker, B.J., Giesy, J.P., Weis, C., Othoudt R, and Vandervoot C. 1991. Bioavailability of Lead in Mining Waste: An Oral Intubation Study in Young Swine. In: The Proceedings of the International Symposium on the Bioavailability and Dietary Uptake of Lead. Science and Technology Letters 3:105-111.
- Mushak, P. 1991. Gastro-intestinal Absorption of Lead in Children and Adults: Overview of Biological and Biophysico-chemical Aspects. In: The Proceedings of the International Symposium on the Bioavailability and Dietary Uptake of Lead. Science and Technology Letters 3:87-104.
- Sherlock, J.C., and Quinn, M.J. 1986. Relationship Between Blood Lead Concentration and Dietary Intake in Infants: the Glasgow Duplicate Diet Study 1979-1980. Food Additives and Contaminants 3:167-176.
- USEPA 1991. Technical Support Document on Lead. United States Environmental Protection Agency, Environmental Criteria and Assessment Office. ECAO-CIN-757.
- USEPA 1994. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children. United States Environmental Protection Agency, Office of Emergency and Remedial Response. Publication Number 9285.7-15-1. EPA/540/R-93/081.
- Weis, C.P. and LaVelle, J.M. 1991. Characteristics to consider when choosing an animal model for the study of lead bioavailability. In: The Proceedings of the International Symposium on the Bioavailability and Dietary Uptake of Lead. Science and Technology Letters 3:113-119.
- Weis, C.P., Henningsen, G.M., Poppenga, R.H., and Thacker, B.J. 1993. Pharmacokinetics of Lead in Blood of Immature Swine Following Acute Oral and Intravenous Exposure. The Toxicologist 13(1):175.
- Weis, C.P., Poppenga, R.H., Thacker, B.J., Henningsen, G.M., and Curtis, A. 1995. "Design of Pharmacokinetic and Bioavailability Studies of Lead in an Immature Swine

Model." In: LEAD IN PAINT, SOIL, AND DUST: HEALTH RISKS, EXPOSURE STUDIES, CONTROL MEASURES, MEASUREMENT METHODS, AND QUALITY ASSURANCE. ASTM STP 1226, Michael E. Beard and S. D. Allen Iske, Eds., American Society for Testing and Materials, Philadelphia, 1995.

APPENDIX A

**DETAILED DATA AND CALCULATIONS FOR
USEPA SWINE BIOAVAILABILITY STUDY
PHASE II, EXPERIMENT 5**

SMUGGLER MOUNTAIN NPL SITE

APPENDIX A

DETAILED DATA SUMMARY

1.0 OVERVIEW

Performance of this study involved collection and reduction of a large number of data items. All of these data items and all of the data reduction steps are contained in a Microsoft Excel spreadsheet named "SMUGGLER.XLS" that is available upon request from the administrative record. This file is intended to allow detailed review and evaluation by outside parties of all aspects of the study.

The following sections of this Appendix present printouts of selected tables and graphs from the XLS file. These tables and graphs provide a more detailed documentation of the individual animal data and the data reduction steps performed in this study than was presented in the main text. Any additional details of interest to a reader can be found in the XLS spreadsheet.

2.0 RAW DATA AND DATA REDUCTION STEPS

2.1 Body Weights and Dose Calculations

Animals were weighed on day -1 (one day before exposure) and every three days thereafter during the course of the study. Doses of lead for the three days following each weighing were based on the group mean body weight, adjusted by addition of 1 kg to account for the expected weight gain over the interval. After completion of the experiment, body weights were estimated by interpolation for those days when measurements were not collected, and the actual administered doses (ug Pb/kg) were calculated for each day and then averaged across all days. If an animal missed a dose or was given an incorrect dose, the calculation of average dose corrected for these factors. (There were no missed or wrong doses in this study). These data and data reduction steps are shown in Tables A-1 and A-2.

2.2 Blood Lead vs Time

Blood lead values were measured in each animal on days -4, 0, 1, 2, 3, 5, 7, 9, 12, and 15. The raw laboratory data (reported as ug/L of diluted blood) are shown in Table A-3. These data were adjusted as follows: a) non-detects were evaluated by assuming a value equal to one-half the quantitation limit, and b) the concentrations in diluted blood were converted to units of ug/dL in whole blood by dividing by a factor of 1 dL of blood per L of diluted sample. The results are shown in the right-hand column of Table A-3. Figures A-1 to A-3 plot the results for individual animals organized by group and by day. Figure A-4 plots the mean for each dosing group by day.

After adjustment as above, values that were more than a factor of 1.5 above or below the group mean for any given day were "flagged" by computer as potential outliers. These values are shown in Table A-4 by cells that are shaded gray. Each data point identified in this way was reviewed and professional judgement was used to decide if the value should be retained or excluded. In order to avoid inappropriate biases, blood lead outlier designations were restricted to values that were clearly aberrant from a time-course and/or dose-response perspective. Those which were judged to warrant exclusion are shown by a heavy black box around the value. All other flagged values were retained.

Rarely, a value not flagged by the computer was judged to be an outlier that should be excluded. These are shown by unshaded cells surrounded by a heavy black box. (There are none in this study).

Table A-5 provided a discussion of the rationale used to decide if a blood lead value should be designated as an outlier or not.

2.3 Blood Lead AUC

The area under the blood lead vs time curve for each animal was calculated by finding the area under the curve for each time step using the trapezoidal rule:

$$\text{AUC}(d_i \text{ to } d_j) = 0.5*(r_i + r_j)*(d_j - d_i)$$

where:

d = day number

r = response (blood lead value) on day i (r_i) or day j (r_j)

The areas were then summed for each of the time intervals to yield the final AUC for each animal. These calculations are shown in Table A-6. If a blood lead value was missing (either because of problems with sample preparation, or because the measured value was excluded as an outlier), the blood lead value for that day was estimated by linear interpolation.

2.4 Liver, Kidney and Bone Lead Data

At sacrifice (day 15), samples of liver, kidney and bone (femur) were removed and analyzed for lead. The raw data (expressed as ug Pb/L of prepared sample) are summarized in Table A-7. These data were adjusted as follows: a) non-detects were evaluated by assuming a value equal to one-half the quantitation limit, and b) the concentrations in prepared sample were converted to units of concentration in the original biological sample by dividing by the following factors:

Liver:	0.1 kg wet weight/L prepared sample
Kidney:	0.1 kg wet weight/L prepared sample
Bone:	2 gm ashed weight/L prepared sample

The resulting values are shown in the right-hand column of Table A-7.

3.0 CURVE FITTING

Basic Equations

A commercial curve-fitting program (Table Curve-2D™ Version 2.0 for Windows, available from Jandel Scientific) was used to derive best fit equations for each of the individual dose-response data sets derived above. A least squares regression method was used for both linear and non-linear equations. As discussed in the text, three different user-defined equations were fit to each data set:

Linear (LIN): Response = $a + b \cdot \text{Dose}$

Exponential (EXP): Response = $a + c \cdot (1 - \exp(-d \cdot \text{Dose}))$

Combination (LIN+EXP): Response = $a + b \cdot \text{Dose} + c \cdot (1 - \exp(-d \cdot \text{Dose}))$

Constraints

In the process of finding the best-fits of these equations to the data, the values of the parameters (a, b, c, and d) were constrained as follows:

- Parameter "a" (the intercept, equal to the baseline or control value of the measurement endpoint) was constrained to be non-negative and was forced in all cases to be the same for the reference material (lead acetate) and the test materials. This is because, by definition, all dose-response curves for groups of animals exposed to different materials must arise from the same value at zero dose. In addition, for blood lead data, "a" was constrained to be equal to the mean of the control group $\pm 20\%$ (typically 7.5 ± 1.5 AUC units).
- Parameter "b" (the slope of the linear dose-response line) was constrained to non-negative values, since all of the measurement endpoints evaluated are observed to increase, not decrease, as a function of lead exposure.
- Parameter "c" (the plateau value of the exponential curve) was constrained to be non-negative, and was forced to be the same for the reference material (lead acetate) and the test material. This is because: 1) it is expected on theoretical grounds that the plateau (saturation level) should be the same regardless of the source of lead, and 2) curve-fitting of individual curves tended to yield values of "c" that were close to each other and were not statistically different.

- Parameter "d" (which determines where the "bend" in the exponential equation occurs) was constrained to be greater than 0.0045 for the lead acetate blood lead (AUC) dose-response curve. This constraint was judged to be necessary because the weight of evidence from all studies clearly showed the lead acetate blood lead dose response curve was non-linear and was best fit by an exponential equation, but in some studies there were only two low doses of lead acetate used to define the dose-response curve, and this narrow range data set could sometimes be fit nearly as well by a linear as an exponential curve. The choice of the constraint on "d" was selected to be slightly lower than the observed best-fit value of "d" (0.006) when data from all lead acetate AUC dose-response curves from all of the different studies in this program were used. This approach may tend to underestimate relative bioavailability slightly in some studies (especially at low dose), but use of the information gained from all studies is judged to be more robust than basing fits solely on the data from one study.

In general, one of these models (the linear, the exponential, or the combination) usually yielded a fit (as judged by the value of the adjusted correlation coefficient R^2 and by visual inspection of the fit of the line through the measured data points) that was clearly superior to the others. If two or more models fit the data approximately equally well, then the simplest model (that with the fewest parameters) was selected.

Outlier Identification

During the dose-response curve fitting process, all data were carefully reviewed to identify any anomalous values. Typically, the process used to identify outliers was as follows:

- Step 1 Any data points judged to be outliers based on information derived from analysis of data across multiple studies (as opposed to conclusions drawn from within the study) were excluded.
- Step 2 The remaining raw data points were fit to the equation judged to be the most likely to be the best fit (linear, exponential, or mixed). Table Curve 2-D was then used to plot the 95% prediction limits around the best fit line. All data points that fell outside the 95% prediction limits were considered to be outliers and were excluded.
- Step 3 After excluding these points (if any), a new best-fit was obtained. In some cases, data points originally inside the 95% prediction limits were now outside the limits. However, further iterative cycles of data point exclusion were not performed, and the fit was considered final.

Curve Fit Results

Table A-8 lists the data used to fit these curves, indicating which endpoints were excluded as outliers and why. Table A-9 shows the type of equation selected to fit each data set, and the best fit parameters. The resulting best-fit equations for the data sets are shown in Figures A-5 to A-16. Values excluded as outliers are represented in the figures by the symbol "+".

4.0 RESULTS -- CALCULATED RBA VALUES

The value of RBA for a test substance was calculated for a series of doses using the following procedure:

1. For each dose, calculate the expected response to test material, using the best fit equation through the dose-response data for that material.
2. For each expected response to test material, calculate the dose of lead acetate that is expected to yield an equivalent response. This is done by "inverting" the dose-response curve for lead acetate, solving for the dose that corresponds to a specified response.
3. Calculate RBA at that dose as the ratio of the dose of lead acetate to the dose of test material. For the situation where both curves are linear, the value of RBA is the ratio of the slopes (the "b" parameters). In the case where both curves are exponential and where both curves have the same values for parameters "a" and "c", the value of RBA is equal to the ratio of the "d" parameters.

The results are summarized in Table A-10.

5.0 QUALITY ASSURANCE DATA

A number of steps were taken throughout this study and the other studies in this project to ensure the quality of the results, including 5% duplicates, 5% standards, a program of interlaboratory comparison. These steps are detailed below.

Duplicates

Duplicate samples were prepared and analyzed for about 5% of all samples generated during the study. Table A-11 lists the first and second values for blood, liver, kidney, and bone. The results are shown in Figure 3-1 in the main text.

Standards

The Centers for Disease Control and Prevention (CDCP) provides a variety of blood lead "check samples" for use in quality assurance programs for blood lead studies. Each time a group of

blood samples was prepared and sent to the laboratory for analysis, several CDCP check samples of different concentrations were included. Table A-12 lists the concentrations reported by the laboratory compared to the nominal concentrations indicated by CDCP for the samples submitted during this study, and the results are plotted in Figure 3-2 in the main text.

Interlaboratory Comparison

An interlaboratory comparison of blood lead analytical results was performed by sending a set of 15 randomly selected whole blood samples from this study to CDCP for independent analysis. The data are presented in Table A-13, and the results are plotted in Figure 3-3 in the main text.

TABLE A-1 BODY WEIGHTS AND ADMINISTERED DOSES, BY DAY

Body weights were measured on days -1, 2, 5, 8, 11, 14. Weights for other days are estimated, based on linear interpolation between measured values.

Group	ID #	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
		BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)	BW (kg)
1	530	9.3	9.6	10.0	10.3	10.6	10.9	11.2	11.5	11.8	12.1	12.4	12.7	13.0	13.3	13.6	13.9	14.2
2	531	9.8	10.1	10.4	10.7	11.0	11.3	11.6	11.9	12.2	12.5	12.8	13.1	13.4	13.7	14.0	14.3	14.6
3	532	10.3	10.6	10.9	11.2	11.5	11.8	12.1	12.4	12.7	13.0	13.3	13.6	13.9	14.2	14.5	14.8	15.1
4	533	10.8	11.1	11.4	11.7	12.0	12.3	12.6	12.9	13.2	13.5	13.8	14.1	14.4	14.7	15.0	15.3	15.6
5	534	11.3	11.6	11.9	12.2	12.5	12.8	13.1	13.4	13.7	14.0	14.3	14.6	14.9	15.2	15.5	15.8	16.1
6	535	11.8	12.1	12.4	12.7	13.0	13.3	13.6	13.9	14.2	14.5	14.8	15.1	15.4	15.7	16.0	16.3	16.6
7	536	12.3	12.6	12.9	13.2	13.5	13.8	14.1	14.4	14.7	15.0	15.3	15.6	15.9	16.2	16.5	16.8	17.1
8	537	12.8	13.1	13.4	13.7	14.0	14.3	14.6	14.9	15.2	15.5	15.8	16.1	16.4	16.7	17.0	17.3	17.6
9	538	13.3	13.6	13.9	14.2	14.5	14.8	15.1	15.4	15.7	16.0	16.3	16.6	16.9	17.2	17.5	17.8	18.1
10	539	13.8	14.1	14.4	14.7	15.0	15.3	15.6	15.9	16.2	16.5	16.8	17.1	17.4	17.7	18.0	18.3	18.6
11	540	14.3	14.6	14.9	15.2	15.5	15.8	16.1	16.4	16.7	17.0	17.3	17.6	17.9	18.2	18.5	18.8	19.1
12	541	14.8	15.1	15.4	15.7	16.0	16.3	16.6	16.9	17.2	17.5	17.8	18.1	18.4	18.7	19.0	19.3	19.6
13	542	15.3	15.6	15.9	16.2	16.5	16.8	17.1	17.4	17.7	18.0	18.3	18.6	18.9	19.2	19.5	19.8	20.1
14	543	15.8	16.1	16.4	16.7	17.0	17.3	17.6	17.9	18.2	18.5	18.8	19.1	19.4	19.7	20.0	20.3	20.6
15	544	16.3	16.6	16.9	17.2	17.5	17.8	18.1	18.4	18.7	19.0	19.3	19.6	19.9	20.2	20.5	20.8	21.1
16	545	16.8	17.1	17.4	17.7	18.0	18.3	18.6	18.9	19.2	19.5	19.8	20.1	20.4	20.7	21.0	21.3	21.6
17	546	17.3	17.6	17.9	18.2	18.5	18.8	19.1	19.4	19.7	20.0	20.3	20.6	20.9	21.2	21.5	21.8	22.1
18	547	17.8	18.1	18.4	18.7	19.0	19.3	19.6	19.9	20.2	20.5	20.8	21.1	21.4	21.7	22.0	22.3	22.6
19	548	18.3	18.6	18.9	19.2	19.5	19.8	20.1	20.4	20.7	21.0	21.3	21.6	21.9	22.2	22.5	22.8	23.1
20	549	18.8	19.1	19.4	19.7	20.0	20.3	20.6	20.9	21.2	21.5	21.8	22.1	22.4	22.7	23.0	23.3	23.6
21	550	19.3	19.6	19.9	20.2	20.5	20.8	21.1	21.4	21.7	22.0	22.3	22.6	22.9	23.2	23.5	23.8	24.1
22	551	19.8	20.1	20.4	20.7	21.0	21.3	21.6	21.9	22.2	22.5	22.8	23.1	23.4	23.7	24.0	24.3	24.6
23	552	20.3	20.6	20.9	21.2	21.5	21.8	22.1	22.4	22.7	23.0	23.3	23.6	23.9	24.2	24.5	24.8	25.1
24	553	20.8	21.1	21.4	21.7	22.0	22.3	22.6	22.9	23.2	23.5	23.8	24.1	24.4	24.7	25.0	25.3	25.6
25	554	21.3	21.6	21.9	22.2	22.5	22.8	23.1	23.4	23.7	24.0	24.3	24.6	24.9	25.2	25.5	25.8	26.1
26	555	21.8	22.1	22.4	22.7	23.0	23.3	23.6	23.9	24.2	24.5	24.8	25.1	25.4	25.7	26.0	26.3	26.6
27	556	22.3	22.6	22.9	23.2	23.5	23.8	24.1	24.4	24.7	25.0	25.3	25.6	25.9	26.2	26.5	26.8	27.1
28	557	22.8	23.1	23.4	23.7	24.0	24.3	24.6	24.9	25.2	25.5	25.8	26.1	26.4	26.7	27.0	27.3	27.6
29	558	23.3	23.6	23.9	24.2	24.5	24.8	25.1	25.4	25.7	26.0	26.3	26.6	26.9	27.2	27.5	27.8	28.1
30	559	23.8	24.1	24.4	24.7	25.0	25.3	25.6	25.9	26.2	26.5	26.8	27.1	27.4	27.7	28.0	28.3	28.6
31	560	24.3	24.6	24.9	25.2	25.5	25.8	26.1	26.4	26.7	27.0	27.3	27.6	27.9	28.2	28.5	28.8	29.1
32	561	24.8	25.1	25.4	25.7	26.0	26.3	26.6	26.9	27.2	27.5	27.8	28.1	28.4	28.7	29.0	29.3	29.6
33	562	25.3	25.6	25.9	26.2	26.5	26.8	27.1	27.4	27.7	28.0	28.3	28.6	28.9	29.2	29.5	29.8	30.1
34	563	25.8	26.1	26.4	26.7	27.0	27.3	27.6	27.9	28.2	28.5	28.8	29.1	29.4	29.7	30.0	30.3	30.6
35	564	26.3	26.6	26.9	27.2	27.5	27.8	28.1	28.4	28.7	29.0	29.3	29.6	29.9	30.2	30.5	30.8	31.1
36	565	26.8	27.1	27.4	27.7	28.0	28.3	28.6	28.9	29.2	29.5	29.8	30.1	30.4	30.7	31.0	31.3	31.6
37	566	27.3	27.6	27.9	28.2	28.5	28.8	29.1	29.4	29.7	30.0	30.3	30.6	30.9	31.2	31.5	31.8	32.1
38	567	27.8	28.1	28.4	28.7	29.0	29.3	29.6	29.9	30.2	30.5	30.8	31.1	31.4	31.7	32.0	32.3	32.6
39	568	28.3	28.6	28.9	29.2	29.5	29.8	30.1	30.4	30.7	31.0	31.3	31.6	31.9	32.2	32.5	32.8	33.1
40	569	28.8	29.1	29.4	29.7	30.0	30.3	30.6	30.9	31.2	31.5	31.8	32.1	32.4	32.7	33.0	33.3	33.6
41	570	29.3	29.6	29.9	30.2	30.5	30.8	31.1	31.4	31.7	32.0	32.3	32.6	32.9	33.2	33.5	33.8	34.1
42	571	29.8	30.1	30.4	30.7	31.0	31.3	31.6	31.9	32.2	32.5	32.8	33.1	33.4	33.7	34.0	34.3	34.6
43	572	30.3	30.6	30.9	31.2	31.5	31.8	32.1	32.4	32.7	33.0	33.3	33.6	33.9	34.2	34.5	34.8	35.1
44	573	30.8	31.1	31.4	31.7	32.0	32.3	32.6	32.9	33.2	33.5	33.8	34.1	34.4	34.7	35.0	35.3	35.6
45	574	31.3	31.6	31.9	32.2	32.5	32.8	33.1	33.4	33.7	34.0	34.3	34.6	34.9	35.2	35.5	35.8	36.1
46	575	31.8	32.1	32.4	32.7	33.0	33.3	33.6	33.9	34.2	34.5	34.8	35.1	35.4	35.7	36.0	36.3	36.6
47	576	32.3	32.6	32.9	33.2	33.5	33.8	34.1	34.4	34.7	35.0	35.3	35.6	35.9	36.2	36.5	36.8	37.1
48	577	32.8	33.1	33.4	33.7	34.0	34.3	34.6	34.9	35.2	35.5	35.8	36.1	36.4	36.7	37.0	37.3	37.6
49	578	33.3	33.6	33.9	34.2	34.5	34.8	35.1	35.4	35.7	36.0	36.3	36.6	36.9	37.2	37.5	37.8	38.1
50	579	33.8	34.1	34.4	34.7	35.0	35.3	35.6	35.9	36.2	36.5	36.8	37.1	37.4	37.7	38.0	38.3	38.6
51	580	34.3	34.6	34.9	35.2	35.5	35.8	36.1	36.4	36.7	37.0	37.3	37.6	37.9	38.2	38.5	38.8	39.1
52	581	34.8	35.1	35.4	35.7	36.0	36.3	36.6	36.9	37.2	37.5	37.8	38.1	38.4	38.7	39.0	39.3	39.6
53	582	35.3	35.6	35.9	36.2	36.5	36.8	37.1	37.4	37.7	38.0	38.3	38.6	38.9	39.2	39.5	39.8	40.1
54	583	35.8	36.1	36.4	36.7	37.0	37.3	37.6	37.9	38.2	38.5	38.8	39.1	39.4	39.7	40.0	40.3	40.6
55	584	36.3	36.6	36.9	37.2	37.5	37.8	38.1	38.4	38.7	39.0	39.3	39.6	39.9	40.2	40.5	40.8	41.1
56	585	36.8	37.1	37.4	37.7	38.0	38.3	38.6	38.9	39.2	39.5	39.8	40.1	40.4	40.7	41.0	41.3	41.6
57	586	37.3	37.6	37.9	38.2	38.5	38.8	39.1	39.4	39.7	40.0	40.3	40.6	40.9	41.2	41.5	41.8	42.1
58	587	37.8	38.1	38.4	38.7	39.0	39.3	39.6	39.9	40.2	40.5	40.8	41.1	41.4	41.7	42.0	42.3	42.6
59	588	38.3	38.6	38.9	39.2	39.5	39.8	40.1	40.4	40.7	41.0	41.3	41.6	41.9	42.2	42.5	42.8	43.1
60	589	38.8	39.1	39.4	39.7	40.0	40.3	40.6	40.9	41.2	41.5	41.8	42.1	42.4	42.7	43.0	43.3	43.6
61	590	39.3	39.6	39.9	40.2	40.5	40.8	41.1	41.4	41.7	42.0	42.3	42.6	42.9	43.2	43.5	43.8	44.1
62	591	39.8	40.1	40.4	40.7	41.0	41.3	41.6	41.9	42.2	42.5	42.8	43.1	43.4	43.7	44.0	44.3	44.6
63	592	40.3	40.6	40.9	41.2	41.5	41.8	42.1	42.4	42.7	43.0	43.3	43.6	43.9	44.2	44.5	44.8	45.1
64	593	40.8	41.1	41.4	41.7	42.0	42.3	42.6	42.9	43.2	43.5	43.8	44.1	44.4	44.7	45.0	45.3	45.6
65	594	41.3	41.6	41.9	42.2	42.5	42.8	43.1	43.4	43.7	44.0	44.3	44.6	44.9	45.2	45.5	45.8	46.1
66	595	41.8	42.1	42.4	42.7	43.0	43.3	43.6	43.9	44.2	44.5	44.8	45.1	45.4	45.7	46.0	46.3	46.6
67	596	42.3	42.6	42.9	43.2	43.5	43.8	44.1	44.4	44.7	45.0	45.3	45.6	45.9	46.2	46.5	46.8	47.1
68	597	42.8	43.1	43.4	43.7	44.0	44.3	44.6	44.9	45.2	45.5	45.8	46.1	46.4	46.7	47.0	47.3	47.6
69	598	43.3	43.6	4														

TABLE A-2
Body Weight Adjusted Doses
(Dose for Day/BW for Day)

Group	ID #	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Avg Dose	Target Dose	% Target	Avg %
1	530	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	0		
1	536	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	0		
2	514	79.9	78.6	77.3	81.6	78.6	75.9	76.3	76.2	74.2	77.9	75.0	72.3	76.0	73.0	70.3	76.3	75		102
2	518	73.1	71.1	69.3	75.5	75.0	74.6	75.6	72.2	69.2	72.8	70.3	68.0	71.5	68.7	66.1	71.5	75		95
2	519	91.9	87.2	83.0	88.8	86.7	84.8	89.4	88.8	88.3	94.9	93.5	92.0	97.4	94.1	90.1	120	75		97
2	520	77.6	75.6	73.8	78.4	76.1	74.0	75.4	72.4	69.7	72.8	69.8	67.1	70.7	68.1	65.7	72.5	75		97
2	524	79.7	75.9	72.4	78.7	77.0	75.9	77.7	75.0	72.4	76.7	74.4	72.3	75.2	71.5	68.1	74.8	75		100
3	501	241.4	227.6	215.3	229.7	223.8	218.3	221.3	211.8	203.0	212.4	203.9	196.0	207.3	200.2	193.6	213.7	225		95
3	513	242.2	226.9	213.3	230.4	227.1	223.8	229.8	222.5	215.6	226.1	217.5	209.5	223.0	216.7	210.8	222.3	225		99
3	529	318.6	287.9	282.6	280.6	273.8	267.2	275.3	267.4	259.9	265.7	249.7	235.5	254.2	250.4	246.7	266.4	225		118
3	534	243.0	226.1	211.5	225.1	218.9	212.9	219.0	212.3	206.0	218.5	212.4	206.6	219.1	212.1	205.6	216.6	225		96
3	547	216.6	203.1	191.2	207.3	205.1	203.0	207.0	199.1	191.8	203.0	198.8	191.0	202.2	195.5	189.2	200.1	225		89
4	503	81.8	77.3	73.2	81.2	78.5	75.9	79.4	76.6	73.9	76.4	73.6	71.0	77.3	73.5	70.1	76.0	75		101
4	523	74.7	73.2	71.8	80.9	79.4	78.0	82.7	80.8	78.9	82.2	79.8	77.6	85.7	82.7	79.8	79.2	75		108
4	532	84.9	79.5	74.7	82.2	79.0	75.9	80.3	78.3	76.4	79.0	76.2	73.6	80.9	77.6	74.6	78.2	75		104
4	549	85.2	80.0	75.5	83.3	80.2	77.3	80.8	77.8	75.1	72.5	65.8	60.3	72.3	75.6	79.2	76.1	75		101
4	555	70.7	67.1	63.8	71.9	70.5	68.2	74.5	73.9	73.3	75.4	72.3	69.5	76.4	73.3	70.5	71.5	75		95
5	509	235.0	224.7	215.3	245.3	241.0	236.9	240.8	231.9	223.6	235.1	227.8	220.9	237.3	230.1	223.3	231.3	225		103
5	512	197.5	189.6	182.4	208.4	205.3	202.3	207.3	201.1	195.3	203.5	195.6	188.3	203.5	198.6	193.8	198.2	225		88
5	539	239.7	226.9	215.3	243.9	238.3	232.9	238.2	230.7	223.6	232.8	223.5	215.0	230.6	223.3	216.4	228.7	225		102
5	540	243.8	229.8	217.2	245.3	239.0	232.9	239.5	233.1	227.1	239.8	233.4	227.3	243.9	236.3	229.1	234.5	225		104
5	550	268.5	248.9	232.0	264.0	259.1	254.3	263.1	257.7	252.5	261.5	249.9	239.2	253.2	242.2	232.1	251.9	225		112
6	510	675.0	643.8	615.3	705.0	681.7	659.9	682.7	665.4	649.0	671.1	648.0	626.4	686.3	641.7	618.8	656.7	675		97
6	516	805.3	742.3	688.4	800.8	785.6	770.9	780.0	744.6	712.3	743.7	724.6	706.5	739.0	700.8	666.3	740.7	675		110
6	525	827.7	772.5	724.2	844.6	830.4	816.7	842.5	818.8	796.5	819.4	787.4	757.7	801.7	768.1	737.2	796.4	675		98
6	537	704.6	660.0	620.8	715.2	695.1	678.1	682.7	650.6	621.4	646.5	627.8	610.1	651.0	628.7	607.9	653.2	675		97
6	542	817.9	772.5	731.8	862.2	856.2	850.4	864.6	829.2	796.5	824.4	787.4	757.7	827.2	816.4	805.8	813.0	675		120
7	502	80.2	73.1	67.2	79.7	79.7	79.7	82.5	80.5	78.5	82.4	80.7	79.1	84.3	81.3	78.6	79.2	75		106
7	507	72.9	69.0	65.5	75.5	73.5	71.6	72.8	69.9	67.1	69.8	67.6	65.7	70.3	68.1	66.0	68.7	75		93
7	517	59.9	56.8	54.0	63.6	63.2	62.8	64.6	62.7	60.8	63.0	60.9	59.0	63.2	61.3	59.5	61.0	75		81
7	522	74.0	70.4	67.2	78.1	76.6	75.1	76.5	73.4	70.5	73.5	71.5	69.6	73.9	71.0	68.3	72.6	75		97
7	528	78.0	72.2	67.2	77.5	75.3	73.3	76.5	75.1	73.8	76.6	74.2	72.0	76.5	73.6	70.9	74.2	75		95
8	505	249.5	229.0	211.6	255.6	252.6	249.8	251.3	241.5	232.4	245.9	236.8	228.3	240.9	232.4	224.5	236.8	225		106
8	506	201.0	189.9	180.0	216.2	212.6	209.0	212.2	205.6	199.5	212.6	206.2	200.1	212.9	207.0	201.4	204.4	225		91
8	521	200.4	187.5	176.1	211.0	207.1	203.3	207.5	202.1	196.9	208.7	201.3	194.4	205.9	199.3	193.1	198.6	225		89
8	553	248.7	229.7	213.5	253.4	246.3	239.6	243.4	236.0	229.0	244.7	237.9	231.4	241.9	231.4	221.8	236.8	225		105
8	554	263.1	242.8	225.4	272.9	270.4	268.0	269.0	256.2	245.4	262.4	255.2	248.3	260.6	250.1	240.4	255.3	225		113
9	526	658.0	618.9	584.2	687.4	681.7	676.1	688.1	660.4	634.9	661.7	643.6	626.4	669.2	647.0	626.2	650.9	675		96
9	535	811.6	753.0	702.3	811.3	790.6	770.9	811.3	803.8	796.5	819.4	787.4	757.7	805.8	775.7	747.8	783.0	675		116
9	541	679.4	634.0	594.2	689.3	674.3	659.9	686.3	672.2	658.8	680.9	657.1	634.9	677.9	655.1	633.8	659.2	675		98
9	545	739.6	695.3	655.9	749.9	723.6	699.0	726.1	710.4	695.4	710.0	677.6	648.0	693.0	670.6	649.7	696.3	675		103
9	548	635.9	606.3	579.4	674.3	661.6	649.5	668.8	649.0	630.3	654.0	633.4	614.1	657.9	637.7	618.8	638.1	675		95
10	504	96.4	94.3	89.7	103.2	100.7	98.3	98.2	94.1	90.4	95.3	92.0	88.9	95.4	93.0	90.6	94.9	100		95
10	508	96.6	91.8	87.5	102.1	101.0	99.9	101.5	96.9	96.5	102.4	99.6	96.8	103.2	99.9	96.8	98.3	100		98
10	515	108.2	101.9	96.3	112.6	111.6	110.6	113.0	110.8	108.6	114.0	109.6	105.5	111.6	107.3	103.2	108.3	100		108
10	538	108.2	101.0	94.6	111.6	111.6	111.6	111.4	108.8	102.6	107.9	104.0	100.3	107.0	103.7	100.6	105.5	100		106
10	543	96.3	91.3	86.8	100.4	98.6	96.8	96.0	91.5	88.4	85.2	84.3	85.2	87.2	84.3	81.5	91.5	100		91
10	544	120.2	113.3	107.1	123.1	119.9	116.9	120.0	118.2	116.4	122.2	117.5	113.1	119.0	113.8	109.0	116.7	100		117
10	546	113.7	106.4	100.0	113.6	109.6	105.9	107.7	105.1	102.6	109.0	106.0	103.2	108.0	102.8	98.0	106.1	100		106
10	551	92.6	86.3	80.8	95.3	95.3	95.3	96.0	92.8	89.8	94.9	91.8	88.9	94.5	91.2	88.1	91.6	100		92

TABLE A - 3 RAW AND ADJUSTED BLOOD LEAD DATA

pig number	sample	group	material administered	dosage	qualifier	lab result (ug/L)	day	source file	MATRIX	Adjusted Value (ug/dL) ^a	Notes
530	8-950139	1	control	0	<	1	-4	pig37.dat	BLOOD	0.5	
536	8-950146	1	control	0	<	1	-4	pig37.dat	BLOOD	0.5	
514	8-950163	2	PbAc	75	<	1	-4	pig37.dat	BLOOD	0.5	
518	8-950122	2	PbAc	75	<	1	-4	pig37.dat	BLOOD	0.5	
519	8-950145	2	PbAc	75	<	1	-4	pig37.dat	BLOOD	0.5	
520	8-950129	2	PbAc	75	<	1	-4	pig37.dat	BLOOD	0.5	
524	8-950172	2	PbAc	75	<	1	-4	pig37.dat	BLOOD	0.5	
501	8-950166	3	PbAc	225	<	1	-4	pig37.dat	BLOOD	0.5	
513	8-950128	3	PbAc	225	<	1	-4	pig37.dat	BLOOD	0.5	
529	8-950147	3	PbAc	225	<	1	-4	pig37.dat	BLOOD	0.5	
534	8-950160	3	PbAc	225	<	1	-4	pig37.dat	BLOOD	0.5	
547	8-950148	3	PbAc	225	<	1	-4	pig37.dat	BLOOD	0.5	
503	8-950162	4	Soil-1	75	<	1	-4	pig37.dat	BLOOD	0.5	
523	8-950131	4	Soil-1	75	<	1	-4	pig37.dat	BLOOD	0.5	
532	8-950171	4	Soil-1	75	<	1	-4	pig37.dat	BLOOD	0.5	
549	8-950124	4	Soil-1	75	<	1	-4	pig37.dat	BLOOD	0.5	
555	8-950156	4	Soil-1	75	<	1	-4	pig37.dat	BLOOD	0.5	
509	8-950153	5	Soil-1	225	<	1	-4	pig37.dat	BLOOD	0.5	
512	8-950157	5	Soil-1	225	<	1	-4	pig37.dat	BLOOD	0.5	
539	8-950161	5	Soil-1	225	<	1	-4	pig37.dat	BLOOD	0.5	
540	8-950165	5	Soil-1	225	<	1	-4	pig37.dat	BLOOD	0.5	
550	8-950170	5	Soil-1	225	<	1	-4	pig37.dat	BLOOD	0.5	
510	8-950123	6	Soil-1	675	<	1	-4	pig37.dat	BLOOD	0.5	
516	8-950169	6	Soil-1	675	<	1	-4	pig37.dat	BLOOD	0.5	
525	8-950168	6	Soil-1	675	<	1	-4	pig37.dat	BLOOD	0.5	
537	8-950167	6	Soil-1	675	<	1	-4	pig37.dat	BLOOD	0.5	
542	8-950137	6	Soil-1	675	<	1	-4	pig37.dat	BLOOD	0.5	
502	8-950149	7	Soil-2	75	<	1	-4	pig37.dat	BLOOD	0.5	
507	8-950130	7	Soil-2	75	<	1	-4	pig37.dat	BLOOD	0.5	
517	8-950125	7	Soil-2	75	<	1	-4	pig37.dat	BLOOD	0.5	
522	8-950142	7	Soil-2	75	<	1	-4	pig37.dat	BLOOD	0.5	
528	8-950132	7	Soil-2	75	<	1	-4	pig37.dat	BLOOD	0.5	
505	8-950159	8	Soil-2	225	<	1	-4	pig37.dat	BLOOD	0.5	
506	8-950134	8	Soil-2	225	<	1	-4	pig37.dat	BLOOD	0.5	
521	8-950164	8	Soil-2	225	<	1	-4	pig37.dat	BLOOD	0.5	
553	8-950151	8	Soil-2	225	<	1	-4	pig37.dat	BLOOD	0.5	
554	8-950174	8	Soil-2	225	<	1	-4	pig37.dat	BLOOD	0.5	
526	8-950143	9	Soil-2	675	<	1	-4	pig37.dat	BLOOD	0.5	
535	8-950135	9	Soil-2	675	<	1	-4	pig37.dat	BLOOD	0.5	
541	8-950136	9	Soil-2	675	<	1	-4	pig37.dat	BLOOD	0.5	
545	8-950158	9	Soil-2	675	<	1	-4	pig37.dat	BLOOD	0.5	
548	8-950126	9	Soil-2	675	<	1	-4	pig37.dat	BLOOD	0.5	
504	8-950141	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
508	8-950173	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
515	8-950154	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
538	8-950155	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
543	8-950127	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
544	8-950150	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
546	8-950140	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
551	8-950133	10	IV	100	<	1	-4	pig37.dat	BLOOD	0.5	
530	8-950178	1	control	0	<	1	0	pig36.dat	BLOOD	0.5	
536	8-950224	1	control	0	<	1	0	pig36.dat	BLOOD	0.5	
514	8-950214	2	PbAc	75	<	1	0	pig36.dat	BLOOD	0.5	
518	8-950222	2	PbAc	75	<	1	0	pig36.dat	BLOOD	0.5	
519	8-950220	2	PbAc	75	<	1	0	pig36.dat	BLOOD	0.5	
520	8-950227	2	PbAc	75	<	1	0	pig36.dat	BLOOD	0.5	
524	8-950228	2	PbAc	75	<	1	0	pig36.dat	BLOOD	0.5	
501	8-950183	3	PbAc	225	<	1	0	pig36.dat	BLOOD	0.5	
513	8-950196	3	PbAc	225	<	1	0	pig36.dat	BLOOD	0.5	
529	8-950211	3	PbAc	225	<	1	0	pig36.dat	BLOOD	0.5	
534	8-950197	3	PbAc	225	<	1	0	pig36.dat	BLOOD	0.5	
547	8-950203	3	PbAc	225	<	1	0	pig36.dat	BLOOD	0.5	
503	8-950218	4	Soil-1	75	<	1	0	pig36.dat	BLOOD	0.5	
523	8-950221	4	Soil-1	75	<	1	0	pig36.dat	BLOOD	0.5	
532	8-950192	4	Soil-1	75	<	1	0	pig36.dat	BLOOD	0.5	
549	8-950177	4	Soil-1	75	<	1	0	pig36.dat	BLOOD	0.5	
555	8-950184	4	Soil-1	75	<	1	0	pig36.dat	BLOOD	0.5	
509	8-950185	5	Soil-1	225	<	1	0	pig36.dat	BLOOD	0.5	
512	8-950191	5	Soil-1	225	<	1	0	pig36.dat	BLOOD	0.5	
539	8-950194	5	Soil-1	225	<	1	0	pig36.dat	BLOOD	0.5	
540	8-950205	5	Soil-1	225	<	1	0	pig36.dat	BLOOD	0.5	
550	8-950187	5	Soil-1	225	<	1	0	pig36.dat	BLOOD	0.5	
510	8-950229	6	Soil-1	675	<	1	0	pig36.dat	BLOOD	0.5	
516	8-950213	6	Soil-1	675	<	1	0	pig36.dat	BLOOD	0.5	
525	8-950209	6	Soil-1	675	<	1	0	pig36.dat	BLOOD	0.5	
537	8-950181	6	Soil-1	675	<	1	0	pig36.dat	BLOOD	0.5	
542	8-950179	6	Soil-1	675	<	1	0	pig36.dat	BLOOD	0.5	
502	8-950189	7	Soil-2	75	<	1	0	pig36.dat	BLOOD	0.5	
507	8-950226	7	Soil-2	75	<	1	0	pig36.dat	BLOOD	0.5	
517	8-950188	7	Soil-2	75	<	1	0	pig36.dat	BLOOD	0.5	
522	8-950206	7	Soil-2	75	<	1	0	pig36.dat	BLOOD	0.5	
528	8-950216	7	Soil-2	75	<	1	0	pig36.dat	BLOOD	0.5	
505	8-950212	8	Soil-2	225	<	1	0	pig36.dat	BLOOD	0.5	
506	8-950198	8	Soil-2	225	<	1	0	pig36.dat	BLOOD	0.5	
521	8-950207	8	Soil-2	225	<	1	0	pig36.dat	BLOOD	0.5	
553	8-950176	8	Soil-2	225	<	1	0	pig36.dat	BLOOD	0.5	
554	8-950190	8	Soil-2	225	<	1	0	pig36.dat	BLOOD	0.5	
526	8-950215	9	Soil-2	675	<	1	0	pig36.dat	BLOOD	0.5	
535	8-950180	9	Soil-2	675	<	1	0	pig36.dat	BLOOD	0.5	

pig number	sample	group	material administered	dosage	qualifier	lab result (ug/L)	day	source file	MATRIX	Adjusted Value (ug/dL) ^a	Notes
521	8-950293	8	Soil-2	225		3.6	2	a.pig38.da	BLOOD	3.6	
523	8-950329	8	Soil-2	225	<	1	2	a.pig38.da	BLOOD	0.5	
554	8-950307	8	Soil-2	225		3.9	2	a.pig38.da	BLOOD	3.9	
526	8-950297	9	Soil-2	675		4.8	2	a.pig38.da	BLOOD	4.8	
535	8-950334	9	Soil-2	675		8.4	2	a.pig38.da	BLOOD	8.4	
541	8-950324	9	Soil-2	675		8.8	2	a.pig38.da	BLOOD	8.8	
545	8-950310	9	Soil-2	675		5.8	2	a.pig38.da	BLOOD	5.8	
548	8-950294	9	Soil-2	675		6.2	2	a.pig38.da	BLOOD	6.2	
504	8-950338	10	IV	100		8.6	2	a.pig38.da	BLOOD	8.6	
508	8-950304	10	IV	100		8.7	2	a.pig38.da	BLOOD	8.7	
515	8-950323	10	IV	100		7.6	2	a.pig38.da	BLOOD	7.6	
538	8-950320	10	IV	100		8.4	2	a.pig38.da	BLOOD	8.4	
543	8-950288	10	IV	100		7.2	2	a.pig38.da	BLOOD	7.2	
544	8-950335	10	IV	100		8	2	a.pig38.da	BLOOD	8	
546	8-950291	10	IV	100		7.2	2	a.pig38.da	BLOOD	7.2	
551	8-950311	10	IV	100		8.1	2	a.pig38.da	BLOOD	8.1	
530	8-950368	1	control	0	<	1	3	a.pig39.da	BLOOD	0.5	
536	8-950347	1	control	0	<	1	3	a.pig39.da	BLOOD	0.5	
514	8-950387	2	PbAc	75		2.3	3	a.pig39.da	BLOOD	2.3	
518	8-950391	2	PbAc	75		3.2	3	a.pig39.da	BLOOD	3.2	
519	8-950349	2	PbAc	75		2.9	3	a.pig39.da	BLOOD	2.9	
520	8-950380	2	PbAc	75		2.9	3	a.pig39.da	BLOOD	2.9	
524	8-950388	2	PbAc	75		1.5	3	a.pig39.da	BLOOD	1.5	
501	8-950382	3	PbAc	225		4.4	3	a.pig39.da	BLOOD	4.4	
513	8-950384	3	PbAc	225		4.8	3	a.pig39.da	BLOOD	4.8	
529	8-950367	3	PbAc	225		8.5	3	a.pig39.da	BLOOD	8.5	
534	8-950344	3	PbAc	225		7.6	3	a.pig39.da	BLOOD	7.6	
547	8-950392	3	PbAc	225		6.3	3	a.pig39.da	BLOOD	6.3	
503	8-950383	4	Soil-1	75	<	1	3	a.pig39.da	BLOOD	0.5	
523	8-950361	4	Soil-1	75		1.1	3	a.pig39.da	BLOOD	1.1	
532	8-950353	4	Soil-1	75		2.3	3	a.pig39.da	BLOOD	2.3	
549	8-950378	4	Soil-1	75		2	3	a.pig39.da	BLOOD	2	
555	8-950343	4	Soil-1	75	<	1	3	a.pig39.da	BLOOD	0.5	
509	8-950354	5	Soil-1	225		5.4	3	a.pig39.da	BLOOD	5.4	
512	8-950371	5	Soil-1	225		3.7	3	a.pig39.da	BLOOD	3.7	
539	8-950345	5	Soil-1	225		6.7	3	a.pig39.da	BLOOD	6.7	
540	8-950364	5	Soil-1	225		4.9	3	a.pig39.da	BLOOD	4.9	
550	8-950356	5	Soil-1	225		5.2	3	a.pig39.da	BLOOD	5.2	
510	8-950359	6	Soil-1	675		8.4	3	a.pig39.da	BLOOD	8.4	
516	8-950352	6	Soil-1	675		6.9	3	a.pig39.da	BLOOD	6.9	
525	8-950373	6	Soil-1	675		5.9	3	a.pig39.da	BLOOD	5.9	
537	8-950389	6	Soil-1	675		9.3	3	a.pig39.da	BLOOD	9.3	
542	8-950372	6	Soil-1	675			3	a.pig39.da	BLOOD		Clotted
502	8-950393	7	Soil-2	75		1.2	3	a.pig39.da	BLOOD	1.2	
507	8-950385	7	Soil-2	75		1.4	3	a.pig39.da	BLOOD	1.4	
517	8-950362	7	Soil-2	75		1.5	3	a.pig39.da	BLOOD	1.5	
522	8-950370	7	Soil-2	75		1.8	3	a.pig39.da	BLOOD	1.8	
528	8-950342	7	Soil-2	75		2.5	3	a.pig39.da	BLOOD	2.5	
505	8-950363	8	Soil-2	225		6.2	3	a.pig39.da	BLOOD	6.2	
506	8-950357	8	Soil-2	225		3.6	3	a.pig39.da	BLOOD	3.6	
521	8-950350	8	Soil-2	225		5.1	3	a.pig39.da	BLOOD	5.1	
553	8-950355	8	Soil-2	225		1.7	3	a.pig39.da	BLOOD	1.7	
554	8-950374	8	Soil-2	225		3.7	3	a.pig39.da	BLOOD	3.7	
526	8-950369	9	Soil-2	675		5.4	3	a.pig39.da	BLOOD	5.4	
535	8-950360	9	Soil-2	675		8.9	3	a.pig39.da	BLOOD	8.9	
541	8-950365	9	Soil-2	675		10.3	3	a.pig39.da	BLOOD	10.3	
545	8-950376	9	Soil-2	675		6.3	3	a.pig39.da	BLOOD	6.3	
548	8-950390	9	Soil-2	675		5.4	3	a.pig39.da	BLOOD	5.4	
504	8-950351	10	IV	100		10.2	3	a.pig39.da	BLOOD	10.2	
508	8-950386	10	IV	100		10.9	3	a.pig39.da	BLOOD	10.9	
515	8-950341	10	IV	100			3	a.pig39.da	BLOOD		Clotted
538	8-950340	10	IV	100			3	a.pig39.da	BLOOD		Clotted
543	8-950379	10	IV	100		8.6	3	a.pig39.da	BLOOD	8.6	
544	8-950358	10	IV	100		10.4	3	a.pig39.da	BLOOD	10.4	
546	8-950346	10	IV	100		9.2	3	a.pig39.da	BLOOD	9.2	
551	8-950381	10	IV	100		9.3	3	a.pig39.da	BLOOD	9.3	
530	8-950407	1	control	0	<	1	5	a.pig35.da	BLOOD	0.5	
536	8-950430	1	control	0	<	1	5	a.pig35.da	BLOOD	0.5	
514	8-950398	2	PbAc	75		2.3	5	a.pig35.da	BLOOD	2.3	
518	8-950449	2	PbAc	75		3.2	5	a.pig35.da	BLOOD	3.2	
519	8-950425	2	PbAc	75		2.4	5	a.pig35.da	BLOOD	2.4	
520	8-950447	2	PbAc	75		2.6	5	a.pig35.da	BLOOD	2.6	
524	8-950431	2	PbAc	75		2.1	5	a.pig35.da	BLOOD	2.1	
501	8-950429	3	PbAc	225		4.8	5	a.pig35.da	BLOOD	4.8	
513	8-950434	3	PbAc	225		5.4	5	a.pig35.da	BLOOD	5.4	
529	8-950422	3	PbAc	225		8.8	5	a.pig35.da	BLOOD	8.8	
534	8-950416	3	PbAc	225		7.8	5	a.pig35.da	BLOOD	7.8	
547	8-950439	3	PbAc	225		5.8	5	a.pig35.da	BLOOD	5.8	
503	8-950448	4	Soil-1	75		1.3	5	a.pig35.da	BLOOD	1.3	
523	8-950436	4	Soil-1	75		1.9	5	a.pig35.da	BLOOD	1.9	
532	8-950433	4	Soil-1	75		3	5	a.pig35.da	BLOOD	3	
549	8-950413	4	Soil-1	75		3.4	5	a.pig35.da	BLOOD	3.4	
555	8-950409	4	Soil-1	75		2	5	a.pig35.da	BLOOD	2	
509	8-950421	5	Soil-1	225		5.1	5	a.pig35.da	BLOOD	5.1	
512	8-950414	5	Soil-1	225		3.5	5	a.pig35.da	BLOOD	3.5	
539	8-950423	5	Soil-1	225		6	5	a.pig35.da	BLOOD	6	
540	8-950418	5	Soil-1	225		4.5	5	a.pig35.da	BLOOD	4.5	
550	8-950406	5	Soil-1	225		6.1	5	a.pig35.da	BLOOD	6.1	
510	8-950396	6	Soil-1	675		8.9	5	a.pig35.da	BLOOD	8.9	
516	8-950417	6	Soil-1	675		9.4	5	a.pig35.da	BLOOD	9.4	
525	8-950401	6	Soil-1	675		8.8	5	a.pig35.da	BLOOD	8.8	
537	8-950419	6	Soil-1	675		11	5	a.pig35.da	BLOOD	11	
542	8-950444	6	Soil-1	675		6.3	5	a.pig35.da	BLOOD	6.3	
502	8-950397	7	Soil-2	75		3.3	5	a.pig35.da	BLOOD	3.3	
507	8-950415	7	Soil-2	75		3.3	5	a.pig35.da	BLOOD	3.3	

Swine Study Phase II Exp 5 Smuggler NPL Site

pig number	sample	group	material administered	dosage	qualifier	lab result (ug/L)	day	source file	MATRIX	Adjusted Value (ug/dL) ^a	Notes
517	8-950427	7	Soil-2	75		2	5	a.pig35.da	BLOOD	2	
522	8-950443	7	Soil-2	75		3	5	a.pig35.da	BLOOD	3	
528	8-950412	7	Soil-2	75		2.6	5	a.pig35.da	BLOOD	2.6	
505	8-950411	8	Soil-2	225		6.2	5	a.pig35.da	BLOOD	6.2	
506	8-950440	8	Soil-2	225		3.5	5	a.pig35.da	BLOOD	3.5	
521	8-950442	8	Soil-2	225		4.4	5	a.pig35.da	BLOOD	4.4	
553	8-950424	8	Soil-2	225		3.4	5	a.pig35.da	BLOOD	3.4	
554	8-950435	8	Soil-2	225		3.4	5	a.pig35.da	BLOOD	3.4	
526	8-950446	9	Soil-2	675		7.4	5	a.pig35.da	BLOOD	7.4	
535	8-950441	9	Soil-2	675		8.8	5	a.pig35.da	BLOOD	8.8	
541	8-950403	9	Soil-2	675		9.9	5	a.pig35.da	BLOOD	9.9	
545	8-950404	9	Soil-2	675		8.8	5	a.pig35.da	BLOOD	8.8	
548	8-950438	9	Soil-2	675		9.6	5	a.pig35.da	BLOOD	9.6	
504	8-950428	10	IV	100		11	5	a.pig35.da	BLOOD	11	
508	8-950426	10	IV	100		12.3	5	a.pig35.da	BLOOD	12.3	
515	8-950437	10	IV	100		11.5	5	a.pig35.da	BLOOD	11.5	
538	8-950395	10	IV	100		11.4	5	a.pig35.da	BLOOD	11.4	
543	8-950405	10	IV	100		10	5	a.pig35.da	BLOOD	10	
544	8-950445	10	IV	100		10.1	5	a.pig35.da	BLOOD	10.1	
546	8-950402	10	IV	100		10.9	5	a.pig35.da	BLOOD	10.9	
551	8-950399	10	IV	100		11.2	5	a.pig35.da	BLOOD	11.2	
530	8-950502	1	control	0	<	1	7	a.pig35.da	BLOOD	0.5	
536	8-950460	1	control	0	<	1	7	a.pig35.da	BLOOD	0.5	
514	8-950492	2	PbAc	75		2.8	7	a.pig35.da	BLOOD	2.8	
518	8-950465	2	PbAc	75		3.4	7	a.pig35.da	BLOOD	3.4	
519	8-950468	2	PbAc	75		3.7	7	a.pig35.da	BLOOD	3.7	
520	8-950453	2	PbAc	75		4.7	7	a.pig35.da	BLOOD	4.7	
524	8-950459	2	PbAc	75		2.7	7	a.pig35.da	BLOOD	2.7	
501	8-950487	3	PbAc	225		7.4	7	a.pig35.da	BLOOD	7.4	
513	8-950472	3	PbAc	225		5.3	7	a.pig35.da	BLOOD	5.3	
529	8-950457	3	PbAc	225		9.4	7	a.pig35.da	BLOOD	9.4	
534	8-950504	3	PbAc	225		9.1	7	a.pig35.da	BLOOD	9.1	
547	8-950500	3	PbAc	225		6.5	7	a.pig35.da	BLOOD	6.5	
503	8-950494	4	Soil-1	75		2.3	7	a.pig35.da	BLOOD	2.3	
523	8-950480	4	Soil-1	75		2.2	7	a.pig35.da	BLOOD	2.2	
532	8-950490	4	Soil-1	75		4.8	7	a.pig35.da	BLOOD	4.8	
549	8-950485	4	Soil-1	75		3.1	7	a.pig35.da	BLOOD	3.1	
555	8-950483	4	Soil-1	75		2.2	7	a.pig35.da	BLOOD	2.2	
509	8-950484	5	Soil-1	225		6	7	a.pig35.da	BLOOD	6	
512	8-950501	5	Soil-1	225		5.1	7	a.pig35.da	BLOOD	5.1	
539	8-950476	5	Soil-1	225		5.8	7	a.pig35.da	BLOOD	5.8	
540	8-950482	5	Soil-1	225		5.3	7	a.pig35.da	BLOOD	5.3	
550	8-950463	5	Soil-1	225		5.8	7	a.pig35.da	BLOOD	5.8	
510	8-950462	6	Soil-1	675		11.3	7	a.pig35.da	BLOOD	11.3	
516	8-950455	6	Soil-1	675		9.8	7	a.pig35.da	BLOOD	9.8	
525	8-950489	6	Soil-1	675		10.1	7	a.pig35.da	BLOOD	10.1	
537	8-950456	6	Soil-1	675		13.8	7	a.pig35.da	BLOOD	13.8	
542	8-950493	6	Soil-1	675		7.4	7	a.pig35.da	BLOOD	7.4	
502	8-950474	7	Soil-2	75		3	7	a.pig35.da	BLOOD	3	
507	8-950466	7	Soil-2	75		3	7	a.pig35.da	BLOOD	3	
517	8-950461	7	Soil-2	75		2.1	7	a.pig35.da	BLOOD	2.1	
522	8-950470	7	Soil-2	75		4.8	7	a.pig35.da	BLOOD	4.8	
528	8-950471	7	Soil-2	75		3.8	7	a.pig35.da	BLOOD	3.8	
505	8-950497	8	Soil-2	225		6.1	7	a.pig35.da	BLOOD	6.1	
506	8-950452	8	Soil-2	225		4.3	7	a.pig35.da	BLOOD	4.3	
521	8-950503	8	Soil-2	225		5.6	7	a.pig35.da	BLOOD	5.6	
553	8-950473	8	Soil-2	225		3.7	7	a.pig35.da	BLOOD	3.7	
554	8-950451	8	Soil-2	225		4.6	7	a.pig35.da	BLOOD	4.6	
526	8-950488	9	Soil-2	675		8.8	7	a.pig35.da	BLOOD	8.8	
535	8-950478	9	Soil-2	675		8.8	7	a.pig35.da	BLOOD	8.8	
541	8-950495	9	Soil-2	675		10.9	7	a.pig35.da	BLOOD	10.9	
545	8-950454	9	Soil-2	675		11	7	a.pig35.da	BLOOD	11	
548	8-950450	9	Soil-2	675		10.8	7	a.pig35.da	BLOOD	10.8	
504	8-950458	10	IV	100		13.8	7	a.pig35.da	BLOOD	13.8	
508	8-950486	10	IV	100		13.6	7	a.pig35.da	BLOOD	13.6	
515	8-950475	10	IV	100		13.1	7	a.pig35.da	BLOOD	13.1	
538	8-950477	10	IV	100		13.3	7	a.pig35.da	BLOOD	13.3	
543	8-950467	10	IV	100		12.2	7	a.pig35.da	BLOOD	12.2	
544	8-950469	10	IV	100		13.8	7	a.pig35.da	BLOOD	13.8	
546	8-950479	10	IV	100		13.1	7	a.pig35.da	BLOOD	13.1	
551	8-950498	10	IV	100		14.3	7	a.pig35.da	BLOOD	14.3	
530	8-950537	1	control	0	<	1	9	pig43.dat	BLOOD	0.5	
536	8-950513	1	control	0	<	1	9	pig43.dat	BLOOD	0.5	
514	8-950553	2	PbAc	75		3.1	9	pig43.dat	BLOOD	3.1	
518	8-950544	2	PbAc	75		3.4	9	pig43.dat	BLOOD	3.4	
519	8-950525	2	PbAc	75		4	9	pig43.dat	BLOOD	4	
520	8-950515	2	PbAc	75		4.6	9	pig43.dat	BLOOD	4.6	
524	8-950555	2	PbAc	75		4.1	9	pig43.dat	BLOOD	4.1	
501	8-950549	3	PbAc	225		7.3	9	pig43.dat	BLOOD	7.3	
513	8-950554	3	PbAc	225		5.9	9	pig43.dat	BLOOD	5.9	
529	8-950526	3	PbAc	225		7.8	9	pig43.dat	BLOOD	7.8	
534	8-950545	3	PbAc	225		10.2	9	pig43.dat	BLOOD	10.2	
547	8-950534	3	PbAc	225		5.6	9	pig43.dat	BLOOD	5.6	
503	8-950542	4	Soil-1	75		2.6	9	pig43.dat	BLOOD	2.6	
523	8-950541	4	Soil-1	75		2.3	9	pig43.dat	BLOOD	2.3	
532	8-950508	4	Soil-1	75		3.6	9	pig43.dat	BLOOD	3.6	
549	8-950509	4	Soil-1	75		3	9	pig43.dat	BLOOD	3	
555	8-950557	4	Soil-1	75		3	9	pig43.dat	BLOOD	3	
509	8-950510	5	Soil-1	225		5.5	9	pig43.dat	BLOOD	5.5	
512	8-950505	5	Soil-1	225		5	9	pig43.dat	BLOOD	5	
539	8-950519	5	Soil-1	225		5.3	9	pig43.dat	BLOOD	5.3	
540	8-950529	5	Soil-1	225		5.7	9	pig43.dat	BLOOD	5.7	
550	8-950547	5	Soil-1	225		4.6	9	pig43.dat	BLOOD	4.6	
510	8-950551	6	Soil-1	675		12.8	9	pig43.dat	BLOOD	12.8	
516	8-950531	6	Soil-1	675		10.1	9	pig43.dat	BLOOD	10.1	

pig number	sample	group	material administered	dosage	qualifier	lab result (ug/L)	day	source file	MATRIX	Adjusted Value (ug/dL) ^a	Notes
525	8-950538	6	Soil-1	675		12	9	pig43.dat	BLOOD	12	
537	8-950556	6	Soil-1	675		16.2	9	pig43.dat	BLOOD	16.2	
542	8-950532	6	Soil-1	675		7.2	9	pig43.dat	BLOOD	7.2	
502	8-950528	7	Soil-2	75		3.1	9	pig43.dat	BLOOD	3.1	
507	8-950536	7	Soil-2	75		3	9	pig43.dat	BLOOD	3	
517	8-950523	7	Soil-2	75		2.5	9	pig43.dat	BLOOD	2.5	
522	8-950530	7	Soil-2	75		4.4	9	pig43.dat	BLOOD	4.4	
528	8-950518	7	Soil-2	75		3.8	9	pig43.dat	BLOOD	3.8	
505	8-950543	8	Soil-2	225		6.5	9	pig43.dat	BLOOD	6.5	
506	8-950522	8	Soil-2	225		3.9	9	pig43.dat	BLOOD	3.9	
521	8-950516	8	Soil-2	225		5.9	9	pig43.dat	BLOOD	5.9	
553	8-950517	8	Soil-2	225		3.5	9	pig43.dat	BLOOD	3.5	
554	8-950552	8	Soil-2	225		4.5	9	pig43.dat	BLOOD	4.5	
526	8-950550	9	Soil-2	675		9.3	9	pig43.dat	BLOOD	9.3	
535	8-950535	9	Soil-2	675		13.7	9	pig43.dat	BLOOD	13.7	
541	8-950540	9	Soil-2	675		11.7	9	pig43.dat	BLOOD	11.7	
545	8-950548	9	Soil-2	675		11.5	9	pig43.dat	BLOOD	11.5	
548	8-950521	9	Soil-2	675		11.3	9	pig43.dat	BLOOD	11.3	
504	8-950512	10	IV	100		12.8	9	pig43.dat	BLOOD	12.8	
508	8-950546	10	IV	100		15	9	pig43.dat	BLOOD	15	
515	8-950507	10	IV	100		14.1	9	pig43.dat	BLOOD	14.1	
538	8-950539	10	IV	100		15.1	9	pig43.dat	BLOOD	15.1	
543	8-950524	10	IV	100		12.5	9	pig43.dat	BLOOD	12.5	
544	8-950558	10	IV	100		12.8	9	pig43.dat	BLOOD	12.8	
546	8-950533	10	IV	100		12.5	9	pig43.dat	BLOOD	12.5	
551	8-950559	10	IV	100		13.1	9	pig43.dat	BLOOD	13.1	
530	8-950561	1	control	0	<	1	12	pig36.dat	BLOOD	0.5	
536	8-950586	1	control	0	<	1	12	pig36.dat	BLOOD	0.5	
514	8-950574	2	PbAc	75		2.5	12	pig36.dat	BLOOD	2.5	
518	8-950578	2	PbAc	75		5.1	12	pig36.dat	BLOOD	5.1	
519	8-950613	2	PbAc	75		4.5	12	pig36.dat	BLOOD	4.5	
520	8-950610	2	PbAc	75		4.5	12	pig36.dat	BLOOD	4.5	
524	8-950597	2	PbAc	75		3.3	12	pig36.dat	BLOOD	3.3	
501	8-950580	3	PbAc	225		8.3	12	pig36.dat	BLOOD	8.3	
513	8-950565	3	PbAc	225		6.9	12	pig36.dat	BLOOD	6.9	
529	8-950585	3	PbAc	225		10.1	12	pig36.dat	BLOOD	10.1	
534	8-950591	3	PbAc	225		11	12	pig36.dat	BLOOD	11	
547	8-950560	3	PbAc	225		6.5	12	pig36.dat	BLOOD	6.5	
503	8-950575	4	Soil-1	75		2.8	12	pig36.dat	BLOOD	2.8	
523	8-950590	4	Soil-1	75		3.6	12	pig36.dat	BLOOD	3.6	
532	8-950607	4	Soil-1	75		5	12	pig36.dat	BLOOD	5	
549	8-950593	4	Soil-1	75		3.4	12	pig36.dat	BLOOD	3.4	
555	8-950612	4	Soil-1	75		3.4	12	pig36.dat	BLOOD	3.4	
509	8-950583	5	Soil-1	225		6.3	12	pig36.dat	BLOOD	6.3	
512	8-950577	5	Soil-1	225		7.4	12	pig36.dat	BLOOD	7.4	
539	8-950571	5	Soil-1	225		6.5	12	pig36.dat	BLOOD	6.5	
540	8-950595	5	Soil-1	225		5.7	12	pig36.dat	BLOOD	5.7	
550	8-950584	5	Soil-1	225		8	12	pig36.dat	BLOOD	8	
510	8-950614	6	Soil-1	675		13.5	12	pig36.dat	BLOOD	13.5	
516	8-950563	6	Soil-1	675		12.1	12	pig36.dat	BLOOD	12.1	
525	8-950594	6	Soil-1	675		13.5	12	pig36.dat	BLOOD	13.5	
537	8-950562	6	Soil-1	675		11.8	12	pig36.dat	BLOOD	11.8	
542	8-950596	6	Soil-1	675		7.9	12	pig36.dat	BLOOD	7.9	
502	8-950581	7	Soil-2	75		4.5	12	pig36.dat	BLOOD	4.5	
507	8-950602	7	Soil-2	75		5.2	12	pig36.dat	BLOOD	5.2	
517	8-950579	7	Soil-2	75		2.7	12	pig36.dat	BLOOD	2.7	
522	8-950592	7	Soil-2	75		5	12	pig36.dat	BLOOD	5	
528	8-950570	7	Soil-2	75		3.5	12	pig36.dat	BLOOD	3.5	
505	8-950576	8	Soil-2	225		8.7	12	pig36.dat	BLOOD	8.7	
506	8-950608	8	Soil-2	225		6.1	12	pig36.dat	BLOOD	6.1	
521	8-950587	8	Soil-2	225		7.2	12	pig36.dat	BLOOD	7.2	
553	8-950605	8	Soil-2	225		5.8	12	pig36.dat	BLOOD	5.8	
554	8-950582	8	Soil-2	225		5.9	12	pig36.dat	BLOOD	5.9	
526	8-950564	9	Soil-2	675		10.1	12	pig36.dat	BLOOD	10.1	
535	8-950569	9	Soil-2	675		17.7	12	pig36.dat	BLOOD	17.7	
541	8-950572	9	Soil-2	675		13.6	12	pig36.dat	BLOOD	13.6	
545	8-950566	9	Soil-2	675		14	12	pig36.dat	BLOOD	14	
548	8-950603	9	Soil-2	675		13.9	12	pig36.dat	BLOOD	13.9	
504	8-950611	10	IV	100		14.3	12	pig36.dat	BLOOD	14.3	
508	8-950598	10	IV	100		16	12	pig36.dat	BLOOD	16	
515	8-950600	10	IV	100		14.1	12	pig36.dat	BLOOD	14.1	
538	8-950601	10	IV	100		16.3	12	pig36.dat	BLOOD	16.3	
543	8-950609	10	IV	100		12.4	12	pig36.dat	BLOOD	12.4	
544	8-950606	10	IV	100		16.4	12	pig36.dat	BLOOD	16.4	
546	8-950588	10	IV	100		14.7	12	pig36.dat	BLOOD	14.7	
551	8-950568	10	IV	100		14.9	12	pig36.dat	BLOOD	14.9	
530	8-950617	1	control	0	<	1	15	pig36.dat	BLOOD	0.5	
536	8-950624	1	control	0	<	1	15	pig36.dat	BLOOD	0.5	
514	8-950633	2	PbAc	75		2.9	15	pig36.dat	BLOOD	2.9	
518	8-950669	2	PbAc	75		6.1	15	pig36.dat	BLOOD	6.1	
519	8-950650	2	PbAc	75		4.4	15	pig36.dat	BLOOD	4.4	
520	8-950659	2	PbAc	75		7.6	15	pig36.dat	BLOOD	7.6	
524	8-950643	2	PbAc	75		4.4	15	pig36.dat	BLOOD	4.4	
501	8-950665	3	PbAc	225		11.8	15	pig36.dat	BLOOD	11.8	
513	8-950619	3	PbAc	225		6.8	15	pig36.dat	BLOOD	6.8	
529	8-950644	3	PbAc	225		9.1	15	pig36.dat	BLOOD	9.1	
534	8-950660	3	PbAc	225		11.2	15	pig36.dat	BLOOD	11.2	
547	8-950645	3	PbAc	225		7.4	15	pig36.dat	BLOOD	7.4	
503	8-950647	4	Soil-1	75		4.1	15	pig36.dat	BLOOD	4.1	
523	8-950658	4	Soil-1	75		3.9	15	pig36.dat	BLOOD	3.9	
532	8-950646	4	Soil-1	75		4.8	15	pig36.dat	BLOOD	4.8	
549	8-950640	4	Soil-1	75		3.1	15	pig36.dat	BLOOD	3.1	
555	8-950655	4	Soil-1	75		3.8	15	pig36.dat	BLOOD	3.8	
509	8-950637	5	Soil-1	225		7.9	15	pig36.dat	BLOOD	7.9	
512	8-950656	5	Soil-1	225		8.3	15	pig36.dat	BLOOD	8.3	

pig number	sample	group	material administered	dosage	qualifier	lab result (ug/L)	day	source file	MATRIX	Adjusted Value (ug/dL) ^a	Notes
539	8-950626	5	Soil-1	225		6.1	15	pig36.dat	BLOOD	6.1	
540	8-950631	5	Soil-1	225		6.7	15	pig36.dat	BLOOD	6.7	
550	8-950616	5	Soil-1	225		6.6	15	pig36.dat	BLOOD	6.6	
510	8-950632	6	Soil-1	675		11.8	15	pig36.dat	BLOOD	11.8	
516	8-950629	6	Soil-1	675		11.9	15	pig36.dat	BLOOD	11.9	
525	8-950654	6	Soil-1	675		14.6	15	pig36.dat	BLOOD	14.6	
537	8-950622	6	Soil-1	675		16.8	15	pig36.dat	BLOOD	16.8	
542	8-950649	6	Soil-1	675		9.3	15	pig36.dat	BLOOD	9.3	
502	8-950667	7	Soil-2	75		4.7	15	pig36.dat	BLOOD	4.7	
507	8-950628	7	Soil-2	75		4	15	pig36.dat	BLOOD	4	
517	8-950653	7	Soil-2	75		2.8	15	pig36.dat	BLOOD	2.8	
522	8-950668	7	Soil-2	75		6.4	15	pig36.dat	BLOOD	6.4	
528	8-950639	7	Soil-2	75		4.1	15	pig36.dat	BLOOD	4.1	
505	8-950625	8	Soil-2	225		9.3	15	pig36.dat	BLOOD	9.3	
506	8-950657	8	Soil-2	225		7.5	15	pig36.dat	BLOOD	7.5	
521	8-950663	8	Soil-2	225		8.8	15	pig36.dat	BLOOD	8.8	
553	8-950641	8	Soil-2	225		5.5	15	pig36.dat	BLOOD	5.5	
554	8-950642	8	Soil-2	225		6.5	15	pig36.dat	BLOOD	6.5	
526	8-950627	9	Soil-2	675		9.3	15	pig36.dat	BLOOD	9.3	
535	8-950636	9	Soil-2	675		16	15	pig36.dat	BLOOD	16	
541	8-950651	9	Soil-2	675		15.7	15	pig36.dat	BLOOD	15.7	
545	8-950621	9	Soil-2	675		13.5	15	pig36.dat	BLOOD	13.5	
548	8-950634	9	Soil-2	675		15.9	15	pig36.dat	BLOOD	15.9	
504	8-950664	10	IV	100		15.2	15	pig36.dat	BLOOD	15.2	
508	8-950662	10	IV	100		17.8	15	pig36.dat	BLOOD	17.8	
515	8-950615	10	IV	100		16.9	15	pig36.dat	BLOOD	16.9	
538	8-950648	10	IV	100		16.4	15	pig36.dat	BLOOD	16.4	
543	8-950623	10	IV	100		12.4	15	pig36.dat	BLOOD	12.4	
544	8-950635	10	IV	100		13.6	15	pig36.dat	BLOOD	13.6	
546	8-950666	10	IV	100		15.4	15	pig36.dat	BLOOD	15.4	
551	8-950652	10	IV	100		15.5	15	pig36.dat	BLOOD	15.5	

^a Non-detects evaluated using 1/2 the quantitation limit; laboratory results (ug/L) converted to concentration in blood (ug/dL) by dividing by dilution factor of 1 dL/L

TABLE A-4 BLOOD LEAD OUTLIERS

Flagged Data Points
Outliers

test material	target dosage	Actual Dose*	group	pig#	BLOOD LEAD (ug/dL) BY DAY									
					-3	0	1	2	3	5	7	9	12	15
Control	0	0.00	1	530	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Control	0	0.00	1	536	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
PbAc	75	76.35	2	514	0.5	0.5	0.5	1	2.3	2.3	2.8	3.1	2.5	2.9
PbAc	75	71.52	2	518	0.5	0.5	1.3	1.5	3.2	3.2	3.4	3.4	5.1	6.1
PbAc	75	90.12	2	519	0.5	0.5	1.1	2	2.9	2.4	3.7	4	4.5	4.4
PbAc	75	72.48	2	520	0.5	0.5	2.5	2	2.9	2.6	4.7	4.6	4.5	7.6
PbAc	75	74.82	2	524	0.5	0.5	1.4	1.1	1.5	2.1	2.7	4.1	3.3	4.4
PbAc	225	213.69	3	501	0.5	0.5	3.8	4.2	4.4	4.8	7.4	7.3	8.3	11.8
PbAc	225	222.34	3	513	0.5	0.5	4.2	3.5	4.8	5.4	5.3	5.9	6.9	6.8
PbAc	225	266.36	3	529	0.5	0.5	5	6.5	8.5	8.8	9.4	7.8	10.1	9.1
PbAc	225	216.61	3	534	0.5	0.5	5	4.8	7.6	7.8	9.1	10.2	11	11.2
PbAc	225	200.13	3	547	0.5	0.5	5.5	5.3	6.3	5.8	6.5	5.6	6.5	7.4
Berm	75	75.97	4	503	0.5	0.5	0.5	0.5	0.5	1.3	2.3	2.6	2.8	4.1
Berm	75	79.22	4	523	0.5	0.5	0.5	0.5	1.1	1.9	2.2	2.3	3.6	3.9
Berm	75	78.20	4	532	0.5	0.5	0.5	0.5	2.3	3	4.8	3.6	5	4.8
Berm	75	76.06	4	549	0.5	0.5	0.5	1.8	2	3.4	3.1	3	3.4	3.1
Berm	75	71.50	4	555	0.5	0.5	0.5	0.5	0.5	2	2.2	3	3.4	3.8
Berm	225	231.27	5	509	0.5	0.5	2.7	3.5	5.4	5.1	6	5.5	6.3	7.9
Berm	225	198.17	5	512	0.5	0.5	2.3	2.6	3.7	3.5	5.1	5	7.4	8.3
Berm	225	228.74	5	539	0.5	0.5	2.9	5	6.7	6	5.8	5.3	6.5	6.1
Berm	225	234.49	5	540	0.5	0.5	4.3	3.8	4.9	4.5	5.3	5.7	5.7	6.7
Berm	225	251.88	5	550	0.5	0.5	3.5	4.6	5.2	6.1	5.8	4.6	8	6.6
Berm	675	656.67	6	510	0.5	0.5	5.8	7.8	8.4	8.9	11.3	12.8	13.5	11.8
Berm	675	740.74	6	516	0.5	0.5	6.3	7.6	6.9	9.4	9.8	10.1	12.1	11.9
Berm	675	796.36	6	525	0.5	0.5	4.9	5.1	5.9	8.8	10.1	12	13.5	14.6
Berm	675	653.24	6	537	0.5	0.5	4.1	7.5	9.3	11	13.8	16.2	11.8	16.8
Berm	675	813.02	6	542	0.5	0.5	3.2	Missing	Missing	6.3	7.4	7.2	7.9	9.3
Residential	75	79.16	7	502	0.5	0.5	0.5	0.5	1.2	3.3	3	3.1	4.5	4.7
Residential	75	69.68	7	507	0.5	0.5	0.5	1.4	1.4	3.3	3	3	5.2	4
Residential	75	61.03	7	517	0.5	0.5	0.5	0.5	1.5	2	2.1	2.5	2.7	2.8
Residential	75	72.65	7	522	0.5	0.5	0.5	Missing	1.8	3	4.8	4.4	5	6.4
Residential	75	74.17	7	528	0.5	0.5	1.2	1.9	2.5	2.6	3.8	3.8	3.5	4.1
Residential	225	238.81	8	505	0.5	0.5	4.7	5	6.2	6.2	6.1	6.5	8.7	9.3
Residential	225	204.42	8	506	0.5	0.5	3	2.5	3.6	3.5	4.3	3.9	6.1	7.5
Residential	225	199.63	8	521	0.5	0.5	2.1	3.6	5.1	4.4	5.6	5.9	7.2	8.8
Residential	225	236.59	8	553	0.5	0.5	2.6	0.5	1.7	3.4	3.7	3.5	5.8	5.5
Residential	225	255.27	8	554	0.5	0.5	2.8	3.9	3.7	3.4	4.6	4.5	5.9	6.5
Residential	675	650.92	9	526	0.5	0.5	1.4	4.8	5.4	7.4	8.8	9.3	10.1	9.3
Residential	675	783.01	9	535	0.5	0.5	7.1	8.4	8.9	8.8	8.8	13.7	17.7	16
Residential	675	659.20	9	541	0.5	0.5	8.2	8.8	10.3	9.9	10.9	11.7	13.6	15.7
Residential	675	696.27	9	545	0.5	0.5	5.4	5.8	6.3	8.8	11	11.5	14	13.5
Residential	675	638.07	9	548	0.5	0.5	4.4	6.2	5.4	9.6	10.8	11.3	13.9	15.9
IV	100	94.91	10	504	0.5	0.5	7.2	8.6	10.2	11	13.8	12.8	14.3	15.2
IV	100	98.31	10	508	0.5	0.5	7.8	8.7	10.9	12.3	13.6	15	16	17.8
IV	100	108.33	10	515	0.5	0.5	6.2	7.6	Missing	11.5	13.1	14.1	14.1	16.9
IV	100	105.52	10	538	0.5	0.5	8.3	8.4	Missing	11.4	13.3	15.1	16.3	16.4
IV	100	91.48	10	543	0.5	0.5	6.5	7.2	8.6	10	12.2	12.5	12.4	12.4
IV	100	116.65	10	544	0.5	0.5	7.8	8	10.4	10.1	13.8	12.8	16.4	13.6
IV	100	106.11	10	546	0.5	0.5	8	7.2	9.2	10.9	13.1	12.5	14.7	15.4
IV	100	91.56	10	551	0.5	0.5	7.2	8.1	9.3	11.2	14.3	13.1	14.9	15.5

* Average Time and Weight-Adjusted Dose for Each Pig

Missing values are a result of clotting in the whole blood, preventing accurate preparation of diluted samples.

TABLE A-5 RATIONALE FOR PbB OUTLIER DECISIONS

OUTLIER	IDENTIFICATION	RATIONALE								
1	Day 12 Group 6 Pig # 537	<p>Based on the time-trend for this animal, the PbB on day 12 is substantially lower than expected from the PbB values measured before and after:</p> <table><tr><td><u>Day</u></td><td><u>PbB</u></td></tr><tr><td>9</td><td>16.2</td></tr><tr><td>12</td><td>11.8</td></tr><tr><td>15</td><td>16.8</td></tr></table> <p>Therefore, this value is excluded and replaced with an interpolated value (16.4 ug/dL).</p>	<u>Day</u>	<u>PbB</u>	9	16.2	12	11.8	15	16.8
<u>Day</u>	<u>PbB</u>									
9	16.2									
12	11.8									
15	16.8									
2	Day 2 Group 8 Pig # 553	<p>Based on comparison with responses by other animals in this group on this day, the response of animal 553 is significantly lower. In addition, it is substantially lower than the value observed in the same animal one day earlier. Therefore, this value is excluded and replaced with an interpolated value of 2.1 ug/dL.</p>								

TABLE A-6 Area Under Curve Determinations

Calculated using interpolated values for missing or excluded data

		AUC (ug/dL-days) For Time Span Shown								AUC Total (ug/dL-days)
group	pig#	0-1	1-2	2-3	3-5	5-7	7-9	9-12	12-15	
1	530	0.50	0.50	0.50	1.00	1.00	1.00	1.50	1.50	7.50
1	536	0.50	0.50	0.50	1.00	1.00	1.00	1.50	1.50	7.50
2	514	0.50	0.75	1.65	4.60	5.10	5.90	8.40	8.10	35.00
2	518	0.90	1.40	2.35	6.40	6.60	6.80	12.75	16.80	54.00
2	519	0.80	1.55	2.45	5.30	6.10	7.70	12.75	13.35	50.00
2	520	1.50	2.25	2.45	5.50	7.30	9.30	13.65	18.15	60.10
2	524	0.95	1.25	1.30	3.60	4.80	6.80	11.10	11.55	41.35
3	501	2.15	4.00	4.30	9.20	12.20	14.70	23.40	30.15	100.10
3	513	2.35	3.85	4.15	10.20	10.70	11.20	19.20	20.55	82.20
3	529	2.75	5.75	7.50	17.30	18.20	17.20	26.85	28.80	124.35
3	534	2.75	4.90	6.20	15.40	16.90	19.30	31.80	33.30	130.55
3	547	3.00	5.40	5.80	12.10	12.30	12.10	18.15	20.85	89.70
4	503	0.50	0.50	0.50	1.80	3.60	4.90	8.10	10.35	30.25
4	523	0.50	0.50	0.80	3.00	4.10	4.50	8.85	11.25	33.50
4	532	0.50	0.50	1.40	5.30	7.80	8.40	12.90	14.70	51.50
4	549	0.50	1.15	1.90	5.40	6.50	6.10	9.60	9.75	40.90
4	555	0.50	0.50	0.50	2.50	4.20	5.20	9.60	10.80	33.80
5	509	1.60	3.10	4.45	10.50	11.10	11.50	17.70	21.30	81.25
5	512	1.40	2.45	3.15	7.20	8.60	10.10	18.60	23.55	75.05
5	539	1.70	3.95	5.85	12.70	11.80	11.10	17.70	18.90	83.70
5	540	2.40	4.05	4.35	9.40	9.80	11.00	17.10	18.60	76.70
5	550	2.00	4.05	4.90	11.30	11.90	10.40	18.90	21.90	85.35
6	510	3.15	6.80	8.10	17.30	20.20	24.10	39.45	37.95	157.05
6	516	3.40	6.95	7.25	16.30	19.20	19.90	33.30	36.00	142.30
6	525	2.70	5.00	5.50	14.70	18.90	22.10	38.25	42.15	149.30
6	537	2.30	5.80	8.40	20.30	24.80	30.00	49.05	49.95	190.60
6	542	1.85	3.59	4.83	11.99	13.70	14.60	22.65	25.80	99.01
7	502	0.50	0.50	0.85	4.50	6.30	6.10	11.40	13.80	43.95
7	507	0.50	0.95	1.40	4.70	6.30	6.00	12.30	13.80	45.95
7	517	0.50	0.50	1.00	3.50	4.10	4.60	7.80	8.25	30.25
7	522	0.50	0.83	1.48	4.80	7.80	9.20	14.10	17.10	55.80
7	528	0.85	1.55	2.20	5.10	6.40	7.60	10.95	11.40	46.05
8	505	2.60	4.85	5.60	12.40	12.30	12.60	22.80	27.00	100.15
8	506	1.75	2.75	3.05	7.10	7.80	8.20	15.00	20.40	66.05
8	521	1.30	2.85	4.35	9.50	10.00	11.50	19.65	24.00	83.15
8	553	1.55	2.38	1.93	5.10	7.10	7.20	13.95	16.95	56.15
8	554	1.65	3.35	3.80	7.10	8.00	9.10	15.60	18.60	67.20
9	526	0.95	3.10	5.10	12.80	16.20	18.10	29.10	29.10	114.45
9	535	3.80	7.75	8.65	17.70	17.60	22.50	47.10	50.55	175.65
9	541	4.35	8.50	9.55	20.20	20.80	22.60	37.95	43.95	167.90
9	545	2.95	5.60	6.05	15.10	19.80	22.50	38.25	41.25	151.50
9	548	2.45	5.30	5.80	15.00	20.40	22.10	37.80	44.70	153.55
10	504	3.85	7.90	9.40	21.20	24.80	26.60	40.65	44.25	178.65
10	508	4.15	8.25	9.80	23.20	25.90	28.60	46.50	50.70	197.10
10	515	3.35	6.90	8.25	20.40	24.60	27.20	42.30	46.50	179.50
10	538	4.40	8.35	8.90	20.80	24.70	28.40	47.10	49.05	191.70
10	543	3.50	6.85	7.90	18.60	22.20	24.70	37.35	37.20	158.30
10	544	4.15	7.90	9.20	20.50	23.90	26.60	43.80	45.00	181.05
10	546	4.25	7.60	8.20	20.10	24.00	25.60	40.80	45.15	175.70
10	551	3.85	7.65	8.70	20.50	25.50	27.40	42.00	45.60	181.20

TABLE A - 7 TISSUE LEAD DATA

pig number	sample	group	material administered	dosage	qualifier	lab result (ug/L) ^a	day	source file	MATRIX	Adjusted Value ^b	Notes
530	8-950867	1	control	0	<	1	15	pg43.dat	FEMUR	0.25	
536	8-950857	1	control	0		1.7	15	pg43.dat	FEMUR	0.85	
514	8-950870	2	PbAc	75		5.6	15	pg43.dat	FEMUR	2.8	
518	8-950833	2	PbAc	75		10.7	15	pg43.dat	FEMUR	5.35	
519	8-950875	2	PbAc	75		11.4	15	pg43.dat	FEMUR	5.7	
520	8-950843	2	PbAc	75			15		FEMUR		
524	8-950864	2	PbAc	75		8.9	15	pg43.dat	FEMUR	4.45	Labelling problem
501	8-950861	3	PbAc	225		37	15	pg43.dat	FEMUR	18.5	
513	8-950826	3	PbAc	225		29.5	15	pg43.dat	FEMUR	14.75	
529	8-950829	3	PbAc	225		27.9	15	pg43.dat	FEMUR	13.95	
534	8-950853	3	PbAc	225		35.4	15	pg43.dat	FEMUR	17.7	
547	8-950834	3	PbAc	225		33.6	15	pg43.dat	FEMUR	16.8	
503	8-950869	4	Soil-1	75		9.5	15	pg43.dat	FEMUR	4.75	
523	8-950865	4	Soil-1	75		6.2	15	pg43.dat	FEMUR	3.1	
532	8-950839	4	Soil-1	75		7.8	15	pg43.dat	FEMUR	3.9	
549	8-950871	4	Soil-1	75		11.5	15	pg43.dat	FEMUR	5.75	
555	8-950824	4	Soil-1	75		5.6	15	pg43.dat	FEMUR	2.8	
509	8-950844	5	Soil-1	225		18.4	15	pg43.dat	FEMUR	9.2	
512	8-950855	5	Soil-1	225			15		FEMUR		
539	8-950838	5	Soil-1	225		19.1	15	pg43.dat	FEMUR	9.55	Labelling problem
540	8-950874	5	Soil-1	225		15.5	15	pg43.dat	FEMUR	7.75	
550	8-950858	5	Soil-1	225		21.7	15	pg43.dat	FEMUR	10.85	
510	8-950851	6	Soil-1	675		71.5	15	pg43.dat	FEMUR	35.75	
516	8-950856	6	Soil-1	675		46.3	15	pg43.dat	FEMUR	23.15	
525	8-950845	6	Soil-1	675		100	15	pg43.dat	FEMUR	50	
537	8-950876	6	Soil-1	675		70.5	15	pg43.dat	FEMUR	35.25	
542	8-950850	6	Soil-1	675		30	15	pg43.dat	FEMUR	15	
502	8-950840	7	Soil-2	75		6.2	15	pg43.dat	FEMUR	3.1	
507	8-950868	7	Soil-2	75		6.7	15	pg43.dat	FEMUR	3.35	
517	8-950836	7	Soil-2	75		5.5	15	pg43.dat	FEMUR	2.75	
522	8-950827	7	Soil-2	75		7	15	pg43.dat	FEMUR	3.5	
528	8-950831	7	Soil-2	75		4.9	15	pg43.dat	FEMUR	2.45	
505	8-950849	8	Soil-2	225		18.6	15	pg43.dat	FEMUR	9.3	
506	8-950828	8	Soil-2	225		41.6	15	pg43.dat	FEMUR	20.8	
521	8-950852	8	Soil-2	225		40.9	15	pg43.dat	FEMUR	20.45	
553	8-950830	8	Soil-2	225		21.2	15	pg43.dat	FEMUR	10.6	
554	8-950854	8	Soil-2	225		16.4	15	pg43.dat	FEMUR	8.2	
526	8-950872	9	Soil-2	675		37	15	pg43.dat	FEMUR	18.5	
535	8-950846	9	Soil-2	675		70.5	15	pg43.dat	FEMUR	35.25	
541	8-950832	9	Soil-2	675		81.5	15	pg43.dat	FEMUR	40.75	
545	8-950860	9	Soil-2	675		53.6	15	pg43.dat	FEMUR	26.8	
548	8-950835	9	Soil-2	675		75	15	pg43.dat	FEMUR	37.5	
504	8-950848	10	IV	100		80.5	15	pg43.dat	FEMUR	40.25	
508	8-950859	10	IV	100		91.5	15	pg43.dat	FEMUR	45.75	
515	8-950847	10	IV	100		104	15	pg43.dat	FEMUR	52	
538	8-950825	10	IV	100		98.5	15	pg43.dat	FEMUR	49.25	
543	8-950837	10	IV	100		80.5	15	pg43.dat	FEMUR	40.25	
544	8-950862	10	IV	100		108	15	pg43.dat	FEMUR	54	
546	8-950866	10	IV	100		87.5	15	pg43.dat	FEMUR	43.75	
551	8-950873	10	IV	100		81	15	pg43.dat	FEMUR	40.5	
530	8-950781	1	control	0	<	2	15	a.pig34.da	KIDNEY	10	
536	8-950795	1	control	0		26.6	15	a.pig34.da	KIDNEY	266	
514	8-950823	2	PbAc	75		14	15	a.pig34.da	KIDNEY	140	
518	8-950777	2	PbAc	75		23.2	15	a.pig34.da	KIDNEY	232	
519	8-950817	2	PbAc	75		18.8	15	a.pig34.da	KIDNEY	188	
520	8-970811	2	PbAc	75			15		KIDNEY		
524	8-950803	2	PbAc	75		14.4	15	a.pig34.da	KIDNEY	144	Labelling problem
501	8-950822	3	PbAc	225		42.4	15	a.pig34.da	KIDNEY	424	
513	8-950794	3	PbAc	225		45.2	15	a.pig34.da	KIDNEY	452	
529	8-950787	3	PbAc	225		55.6	15	a.pig34.da	KIDNEY	556	
534	8-950790	3	PbAc	225		71.8	15	a.pig34.da	KIDNEY	718	
547	8-950779	3	PbAc	225		61.2	15	a.pig34.da	KIDNEY	612	
503	8-950792	4	Soil-1	75		35.2	15	a.pig34.da	KIDNEY	352	
523	8-950799	4	Soil-1	75		11.2	15	a.pig34.da	KIDNEY	112	
532	8-950813	4	Soil-1	75		14.2	15	a.pig34.da	KIDNEY	142	
549	8-950815	4	Soil-1	75		12.2	15	a.pig34.da	KIDNEY	122	
555	8-950806	4	Soil-1	75		8.8	15	a.pig34.da	KIDNEY	88	
509	8-950775	5	Soil-1	225		45	15	a.pig34.da	KIDNEY	450	
512	8-950816	5	Soil-1	225			15		KIDNEY		
539	8-950800	5	Soil-1	225		39.4	15	a.pig34.da	KIDNEY	394	Labelling problem
540	8-950774	5	Soil-1	225		86	15	a.pig34.da	KIDNEY	860	
550	8-950772	5	Soil-1	225		47.4	15	a.pig34.da	KIDNEY	474	
510	8-950797	6	Soil-1	675		95.4	15	a.pig34.da	KIDNEY	954	
516	8-950793	6	Soil-1	675		82	15	a.pig34.da	KIDNEY	820	
525	8-950780	6	Soil-1	675		151	15	a.pig34.da	KIDNEY	1510	
537	8-950819	6	Soil-1	675		100	15	a.pig34.da	KIDNEY	1000	
542	8-950778	6	Soil-1	675		35.2	15	a.pig34.da	KIDNEY	352	
502	8-950791	7	Soil-2	75		15.2	15	a.pig34.da	KIDNEY	152	
507	8-950789	7	Soil-2	75		15.8	15	a.pig34.da	KIDNEY	158	
517	8-950820	7	Soil-2	75		7	15	a.pig34.da	KIDNEY	70	
522	8-950812	7	Soil-2	75		15.6	15	a.pig34.da	KIDNEY	156	
528	8-950802	7	Soil-2	75		11	15	a.pig34.da	KIDNEY	110	
505	8-950821	8	Soil-2	225		26	15	a.pig34.da	KIDNEY	260	
506	8-950771	8	Soil-2	225		91	15	a.pig34.da	KIDNEY	910	
521	8-950814	8	Soil-2	225		33.6	15	a.pig34.da	KIDNEY	336	
553	8-950804	8	Soil-2	225		43.6	15	a.pig34.da	KIDNEY	436	
554	8-950810	8	Soil-2	225		26	15	a.pig34.da	KIDNEY	260	
526	8-950798	9	Soil-2	675		74.6	15	a.pig34.da	KIDNEY	746	
535	8-950801	9	Soil-2	675		140	15	a.pig34.da	KIDNEY	1400	

pig number	sample	group	material administered	dosage	qualifier	lab result (ug/L) ^a	day	source file	MATRIX	Adjusted Value ^b	Notes
541	8-950807	9	Soil-2	675		163	15	a.pig34.da	KIDNEY	1630	
545	8-950796	9	Soil-2	675		128	15	a.pig34.da	KIDNEY	1280	
548	8-950773	9	Soil-2	675		101	15	a.pig34.da	KIDNEY	1010	
504	8-950805	10	IV	100		91.6	15	a.pig34.da	KIDNEY	916	
508	8-950808	10	IV	100		146	15	a.pig34.da	KIDNEY	1460	
515	8-950818	10	IV	100		134	15	a.pig34.da	KIDNEY	1340	
538	8-950783	10	IV	100		161	15	a.pig34.da	KIDNEY	1610	
543	8-950776	10	IV	100		142	15	a.pig34.da	KIDNEY	1420	
544	8-950785	10	IV	100		144	15	a.pig34.da	KIDNEY	1440	
546	8-950809	10	IV	100		98.2	15	a.pig34.da	KIDNEY	982	
551	8-950784	10	IV	100		139	15	a.pig34.da	KIDNEY	1390	
530	8-950722	1	control	0		3	15	pig36.dat	LIVER	30	
536	8-950737	1	control	0		22.6	15	pig36.dat	LIVER	226	
514	8-950754	2	PbAc	75		13.4	15	pig36.dat	LIVER	134	
518	8-950721	2	PbAc	75		26	15	pig36.dat	LIVER	260	
519	8-950753	2	PbAc	75		24.4	15	pig36.dat	LIVER	244	
520	8-970736	2	PbAc	75			15		LIVER		Labelling problem
524	8-950745	2	PbAc	75		13.4	15	pig36.dat	LIVER	134	
501	8-950723	3	PbAc	225		57.4	15	pig36.dat	LIVER	574	
513	8-950746	3	PbAc	225		35.6	15	pig36.dat	LIVER	356	
529	8-950759	3	PbAc	225		48.4	15	pig36.dat	LIVER	484	
534	8-950725	3	PbAc	225		77.2	15	pig36.dat	LIVER	772	
547	8-950742	3	PbAc	225		66	15	pig36.dat	LIVER	660	
503	8-950763	4	Soil-1	75		37.8	15	pig36.dat	LIVER	378	
523	8-950729	4	Soil-1	75		10.8	15	pig36.dat	LIVER	108	
532	8-950726	4	Soil-1	75		15	15	pig36.dat	LIVER	150	
549	8-950727	4	Soil-1	75		17.4	15	pig36.dat	LIVER	174	
555	8-950719	4	Soil-1	75		16.2	15	pig36.dat	LIVER	162	
509	8-950738	5	Soil-1	225		55.4	15	pig36.dat	LIVER	554	
512	8-950728	5	Soil-1	225			15		LIVER		Labelling problem
539	8-950724	5	Soil-1	225		39.4	15	pig36.dat	LIVER	394	
540	8-950741	5	Soil-1	225		54.6	15	pig36.dat	LIVER	546	
550	8-950764	5	Soil-1	225		51.2	15	pig36.dat	LIVER	512	
510	8-950767	6	Soil-1	675		155	15	pig36.dat	LIVER	1550	
516	8-950733	6	Soil-1	675		64.6	15	pig36.dat	LIVER	646	
525	8-950744	6	Soil-1	675		186	15	pig36.dat	LIVER	1860	
537	8-950766	6	Soil-1	675		181	15	pig36.dat	LIVER	1810	
542	8-950718	6	Soil-1	675		49.2	15	pig36.dat	LIVER	492	
502	8-950743	7	Soil-2	75		15.2	15	pig36.dat	LIVER	152	
507	8-950762	7	Soil-2	75		15.8	15	pig36.dat	LIVER	158	
517	8-950720	7	Soil-2	75		476	15	pig36.dat	LIVER	4760	
522	8-950751	7	Soil-2	75		13.2	15	pig36.dat	LIVER	132	
528	8-950735	7	Soil-2	75		8.6	15	pig36.dat	LIVER	86	
505	8-950760	8	Soil-2	225		41.6	15	pig36.dat	LIVER	416	
506	8-950740	8	Soil-2	225		60	15	pig36.dat	LIVER	600	
521	8-950770	8	Soil-2	225		37.6	15	pig36.dat	LIVER	376	
553	8-950747	8	Soil-2	225		54.2	15	pig36.dat	LIVER	542	
554	8-950769	8	Soil-2	225		39	15	pig36.dat	LIVER	390	
526	8-950768	9	Soil-2	675		62.4	15	pig36.dat	LIVER	624	
535	8-950749	9	Soil-2	675		194	15	pig36.dat	LIVER	1940	
541	8-950752	9	Soil-2	675		210	15	pig36.dat	LIVER	2100	
545	8-950750	9	Soil-2	675		88.6	15	pig36.dat	LIVER	886	
548	8-950756	9	Soil-2	675		132	15	pig36.dat	LIVER	1320	
504	8-950731	10	IV	100		82	15	pig36.dat	LIVER	820	
508	8-950739	10	IV	100		196	15	pig36.dat	LIVER	1960	
515	8-950755	10	IV	100		190	15	pig36.dat	LIVER	1900	
538	8-950748	10	IV	100		150	15	pig36.dat	LIVER	1500	
543	8-950730	10	IV	100		151	15	pig36.dat	LIVER	1510	
544	8-950761	10	IV	100		145	15	pig36.dat	LIVER	1450	
546	8-950758	10	IV	100		185	15	pig36.dat	LIVER	1850	
551	8-950734	10	IV	100		196	15	pig36.dat	LIVER	1960	

a Blanks are samples which were not analyzed due to a labelling problem at necropsy

b Non-detects evaluated using 1/2 the quantitation limit. Laboratory results (ug/L) converted to tissue concentrations by dividing by sample dilution factors of 0.1 kg/L (liver, kidney) or 2 g/L (ashed bone). Final units are ug Pb/kg wet weight (liver, kidney) or ug Pb/g ashed bone (femur).

TABLE A-8 SUMMARY OF ENDPOINT OUTLIERS

 Selected Outliers

test material	target dosage	Actual Dose*	group	pig#	MEASUREMENT ENDPOINT			
					Blood	Femur	Liver	Kidney
Control	0	0.00	1	530	7.5	0.25	30	10
Control	0	0.00	1	536	7.5	0.85	226 a1	266 a1
PbAc	75	76.35	2	514	35.0	2.8	134	140
PbAc	75	71.52	2	518	54.0	5.35	260	232
PbAc	75	90.12	2	519	50.0	5.7	244	188
PbAc	75	72.48	2	520	60.1	Missing	Missing	Missing
PbAc	75	74.82	2	524	41.4	4.45	134	144
PbAc	225	213.69	3	501	100.1	18.5	574	424
PbAc	225	222.34	3	513	82.2	14.75	356	452
PbAc	225	266.36	3	529	124.4	13.95	484	556
PbAc	225	216.61	3	534	130.6	17.7	772	718
PbAc	225	200.13	3	547	89.7	16.8	660	612
Berm	75	75.97	4	503	30.3	4.75	378	352
Berm	75	79.22	4	523	33.5	3.1	108	112
Berm	75	78.20	4	532	51.5	3.9	150	142
Berm	75	76.06	4	549	40.9	5.75	174	122
Berm	75	71.50	4	555	33.8	2.8	162	88
Berm	225	231.27	5	509	81.3	9.2	554	450
Berm	225	198.17	5	512	75.1	Missing	Missing	Missing
Berm	225	228.74	5	539	83.7	9.55	394	394
Berm	225	234.49	5	540	76.7	7.75	546	860
Berm	225	251.88	5	550	85.4	10.85	512	474
Berm	675	656.67	6	510	157.1	35.75	1550	954
Berm	675	740.74	6	516	142.3	23.15	646	820
Berm	675	796.36	6	525	149.3	50	1860	1510
Berm	675	653.24	6	537	190.6 b	35.25	1810	1000
Berm	675	813.02	6	542	99.0 b	15 b	492 c	352 b
Residential	75	79.16	7	502	44.0	3.1	152	152
Residential	75	69.68	7	507	46.0	3.35	158	158
Residential	75	61.03	7	517	30.3	2.75	4760 a2	70
Residential	75	72.65	7	522	55.8	3.5	132	156
Residential	75	74.17	7	528	46.1	2.45	86	110
Residential	225	238.81	8	505	100.2	9.3	416	260
Residential	225	204.42	8	506	66.1	20.8	600	910 b
Residential	225	199.63	8	521	83.2	20.45	376	336
Residential	225	236.59	8	553	56.2	10.6	542	436
Residential	225	255.27	8	554	67.2	8.2	390	260
Residential	675	650.92	9	526	114.5	18.5	624	746
Residential	675	783.01	9	535	175.7	35.25	1940	1400
Residential	675	659.20	9	541	167.9	40.75	2100 b	1630
Residential	675	696.27	9	545	151.5	26.8	886	1280
Residential	675	638.07	9	548	153.6	37.5	1320	1010
IV	100	94.91	10	504	178.7	40.25	820	916
IV	100	98.31	10	508	197.1	45.75	1960	1460
IV	100	108.33	10	515	179.5	52	1900	1340
IV	100	105.52	10	538	191.7	49.25	1500	1610
IV	100	91.48	10	543	158.3	40.25	1510	1420
IV	100	116.65	10	544	181.1	54	1450	1440
IV	100	106.11	10	546	175.7	43.75	1850	982
IV	100	91.56	10	551	181.2	40.5	1960	1390

a a priori outlier determinations

- a1 - These two control values were excluded based on the fact that the values were out of normal range when compared to control data across all studies. In addition, the values were higher than those for the low dose PbAc group
- a2 - This value is clearly higher than others in the same dose group or higher dose groups. This value was judged to be anomalous and excluded on this basis.

b Outside 95% Prediction Interval

- c Professional Judgement - This data point was borderline for exclusion based on the 95th% prediction interval. Since data for the other 3 endpoints for this animal were excluded, it was determined that this point should be considered an outlier as well.

TABLE A-9 Best Curve Fit Parameters

BLOOD		BONE		LIVER		KIDNEY	
PbAc Curve -	Exp	PbAc Curve -	Linear	PbAc Curve -	Linear	PbAc Curve -	Linear
a	7.57	a	0.494	a	33.04	a	23.5
b		b	0.068	b	2.318	b	2.3
c	170.2	c		c		c	
d	0.0045	d		d		d	
R2	0.882	R2	0.905	R2	0.789	R2	0.882
Berm Curve -		Berm Curve -		Berm Curve -		Berm Curve -	
PbAc Curve -	Exp	PbAc Curve -	Linear	PbAc Curve -	Linear	PbAc Curve -	Linear
a	7.57	a	0.494	a	33.04	a	23.5
b		b	0.0487	b	1.993	b	1.56
c	170.2	c		c		c	
d	0.0025	d		d		d	
R2	0.986	R2	0.891	R2	0.806	R2	0.799
Residential Curve -		Residential Curve -		Residential Curve -		Residential Curve -	
PbAc Curve -	Exp	PbAc Curve -	Linear	PbAc Curve -	Linear	PbAc Curve -	Linear
a	7.57	a	0.494	a	33.04	a	23.5
b		b	0.0464	b	1.723	b	1.698
c	170.2	c		c		c	
d	0.0026	d		d		d	
R2	0.925	R2	0.819	R2	0.76	R2	0.875

Equations Used

EXP $Y=a+c*(1-\exp(-d*dose))$ LIN $Y=a+b*dose$

TABLE A-10 Relative Bioavailability of Lead in Test Materials

Endpoint	Test Material	
	Berm	Residential
Blood	0.56	0.58
Liver	0.86	0.74
Kidney	0.68	0.74
Bone	0.72	0.68

Definitions

Plausible Range: RBA(Blood) to mean RBA for Tissues

Preferred Range: RBA(Blood) to $(\text{RBA}(\text{Blood}) + \text{RBA}(\text{Tissues}))/2$

Suggested Point Est: $1/2(\text{RBA}(\text{Blood}) + (\text{RBA}(\text{Blood}) + \text{RBA}(\text{Tissues}))/2)$

Relative Bioavailability

	Berm		Residential	
Plausible Range	0.56	0.75	0.58	0.72
Preferred Range	0.56	0.65	0.58	0.65
Point Estimate	0.60		0.61	

Absolute Bioavailability

	Berm		Residential	
Plausible Range	28%	38%	29%	36%
Preferred Range	28%	33%	29%	32%
Point Estimate	30%		31%	

TABLE A-11 INTRALABORATORY DUPLICATES

RPD = Relative Percent Difference
 $RPD = 100 * [Orig-Dup] / ((Orig+Dup)/2)$

* Non detects evaluated at 1/2 DL

Pig number	group	material administered	dosage	day	matrix	Duplicate Value*	Original Value*	Average	RPD	Avg RPD
530	1	control	0	0	BLOOD	0.5	0.5	0.5	0%	
536	1	control	0	3	BLOOD	0.5	0.5	0.5	0%	
530	1	control	0	15	BLOOD	0.5	0.5	0.5	0%	
520	2	PbAc	75	7	BLOOD	4.3	4.7	4.5	9%	
547	3	PbAc	225	-4	BLOOD	0.5	0.5	0.5	0%	
529	3	PbAc	225	0	BLOOD	0.5	0.5	0.5	0%	
547	3	PbAc	225	0	BLOOD	0.5	0.5	0.5	0%	
529	3	PbAc	225	2	BLOOD	6.3	6.5	6.4	3%	
513	3	PbAc	225	15	BLOOD	6.6	6.8	6.7	3%	
532	4	Soil-1	75	9	BLOOD	3.9	3.6	3.75	-8%	
549	4	Soil-1	75	9	BLOOD	2.6	3	2.8	14%	
540	5	Soil-1	225	3	BLOOD	4.3	4.9	4.6	13%	
509	5	Soil-1	225	9	BLOOD	5.9	5.5	5.7	-7%	
510	6	Soil-1	675	5	BLOOD	9.4	8.9	9.15	-5%	
516	6	Soil-1	675	12	BLOOD	13.1	12.1	12.6	-8%	
537	6	Soil-1	675	12	BLOOD	10.6	13.5	12.05	24%	
507	7	Soil-2	75	-4	BLOOD	0.5	0.5	0.5	0%	
502	7	Soil-2	75	5	BLOOD	3	3.3	3.15	10%	
505	8	Soil-2	225	1	BLOOD	4.3	4.7	4.5	9%	
506	8	Soil-2	225	1	BLOOD	3.4	3	3.2	-13%	
554	8	Soil-2	225	2	BLOOD	3.7	3.9	3.8	5%	
553	8	Soil-2	225	3	BLOOD	2	1.7	1.85	-16%	
506	8	Soil-2	225	7	BLOOD	4.2	4.3	4.25	2%	
545	9	Soil-2	675	7	BLOOD	11.4	11	11.2	-4%	
526	9	Soil-2	675	12	BLOOD	9.7	10.1	9.9	4%	
545	9	Soil-2	675	15	BLOOD	15.1	13.5	14.3	-11%	
551	10	IV	100	-4	BLOOD	0.5	0.5	0.5	0%	
515	10	IV	100	1	BLOOD	6.1	6.2	6.15	2%	
538	10	IV	100	2	BLOOD	7.8	8.4	8.1	7%	
538	10	IV	100	5	BLOOD	11.8	11.4	11.6	-3%	1% BLOOD
547	3	PbAc	225	15	FEMUR	26.9	33.6	30.25	22%	
507	7	Soil-2	75	15	FEMUR	6.7	6.7	6.7	0%	
551	10	IV	100	15	FEMUR	92	81	86.5	-13%	3% FEMUR
547	3	PbAc	225	15	KIDNEY	54.4	61.2	57.8	12%	
507	7	Soil-2	75	15	KIDNEY	16.4	15.8	16.1	-4%	
551	10	IV	100	15	KIDNEY	158	139	148.5	-13%	-2% KIDNEY
547	3	PbAc	225	15	LIVER	72	66	69	-9%	
507	7	Soil-2	75	15	LIVER	16	15.8	15.9	-1%	
551	10	IV	100	15	LIVER	180	196	188	9%	0% LIVER

TABLE A-12 CDC STANDARDS

Sample ID	Day	Q	Measured*		Nominal	
			Low Std	Med Std	Low Std	Med Std
5.1	-4		1		1.7	4.8
5.1	0	<	1		1.7	4.8
5.1	1	<	1		1.7	4.8
5.1	2	<	1		1.7	4.8
5.1	3	<	1		1.7	4.8
5.1	5		1		1.7	4.8
5.1	7		1		1.7	4.8
5.1	9	<	1		1.7	4.8
5.1	12	<	1		1.7	4.8
5.1	15	<	1		1.7	4.8
5.2	-4			3.6		
5.2	0			4.2		
5.2	1			4.1		
5.2	2			3.6		
5.2	3			3.3		
5.2	5			4.4		
5.2	7			4.0		
5.2	9			4.2		
5.2	12			3.9		
5.2	15			3.8		

* Non-detects evaluated at the detection limit

TABLE A-13 INTERLABORATORY COMPARISON

Tag Number	Pig Number	Group	Material Administered	Dosage	Qualifier		CDC	Result		Average	RPD
					CDC	ESD		ESD			
8-950129	520	2	PbAc	75	U	<	0.6	1	0.8	50	
8-950134	506	8	Soil-2	225	U	<	0.6	1	0.8	50	
8-950213	516	6	Soil-1	675	U	<	0.6	1	0.8	50	
8-950226	507	7	Soil-2	75	U	<	0.6	1	0.8	50	
8-950240	554	8	Soil-2	225			4.4	2.8	3.6	-44	
8-950281	542	6	Soil-1	675			3.8	3.2	3.5	-17	
8-950293	521	8	Soil-2	225			4.6	3.6	4.1	-24	
8-950326	520	2	PbAc	75			3	2	2.5	-40	
8-950381	551	10	IV	100			11.2	9.3	10.25	-19	
8-950390	548	9	Soil-2	675			7	5.4	6.2	-26	
8-950395	538	10	IV	100			13.9	11.4	12.65	-20	
8-950407	530	1	control	0	U	<	0.6	1	0.8	50	
8-950450	548	9	Soil-2	675			12.7	10.8	11.75	-16	
8-950451	554	8	Soil-2	225			5.1	4.6	4.85	-10	
8-950505	512	5	Soil-1	225			6.3	5	5.65	-23	
8-950507	515	10	IV	100			17.8	14.1	15.95	-23	
8-950560	547	3	PbAc	225			7.6	6.5	7.05	-16	
8-950561	530	1	control	0	U	<	0.6	1	0.8	50	
8-950615	515	10	IV	100			21.8	16.9	19.35	-25	
8-950616	550	5	Soil-1	225			9.4	6.6	8	-35	

FIGURE A-1 PbAc and IV Groups by Day
Raw Data

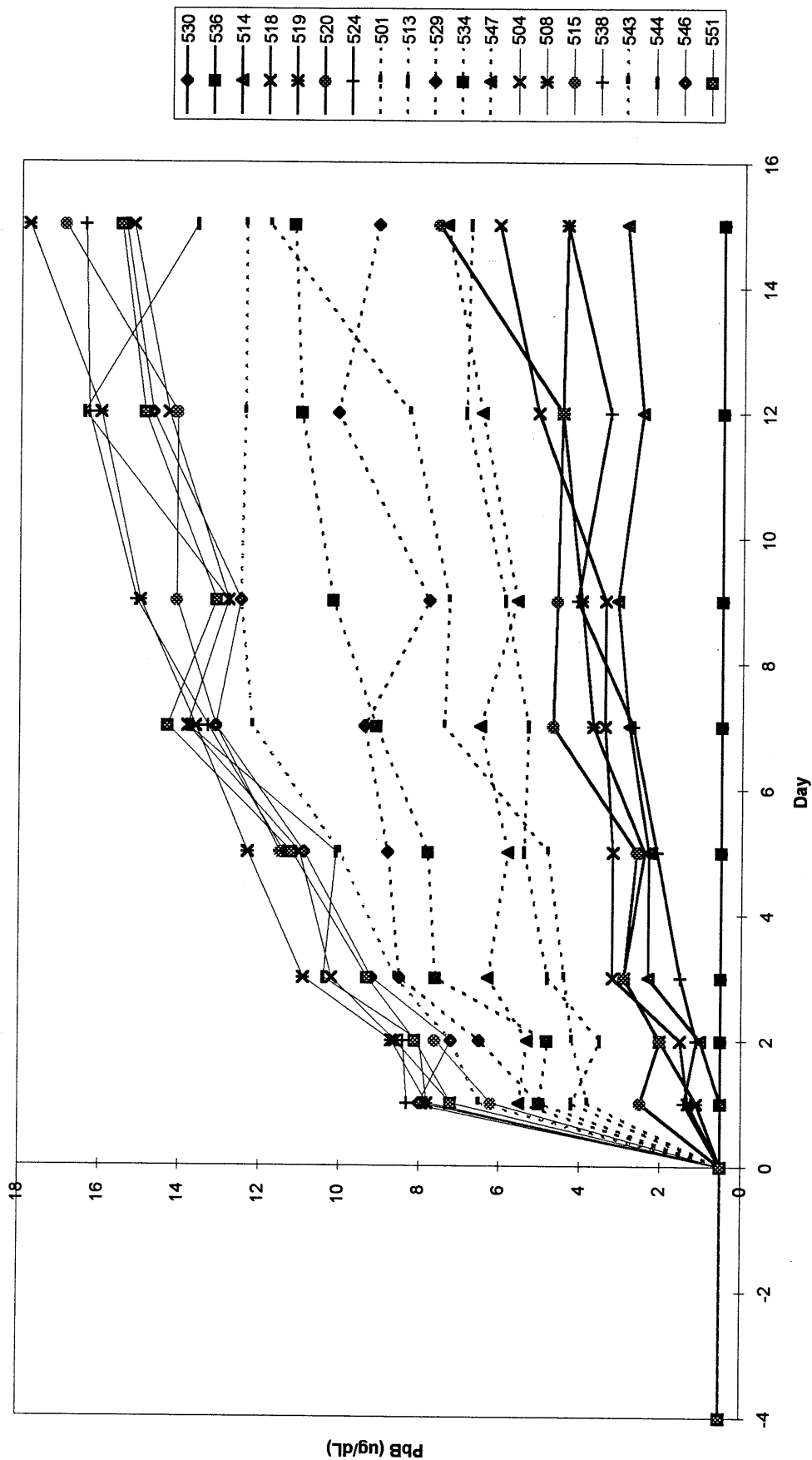
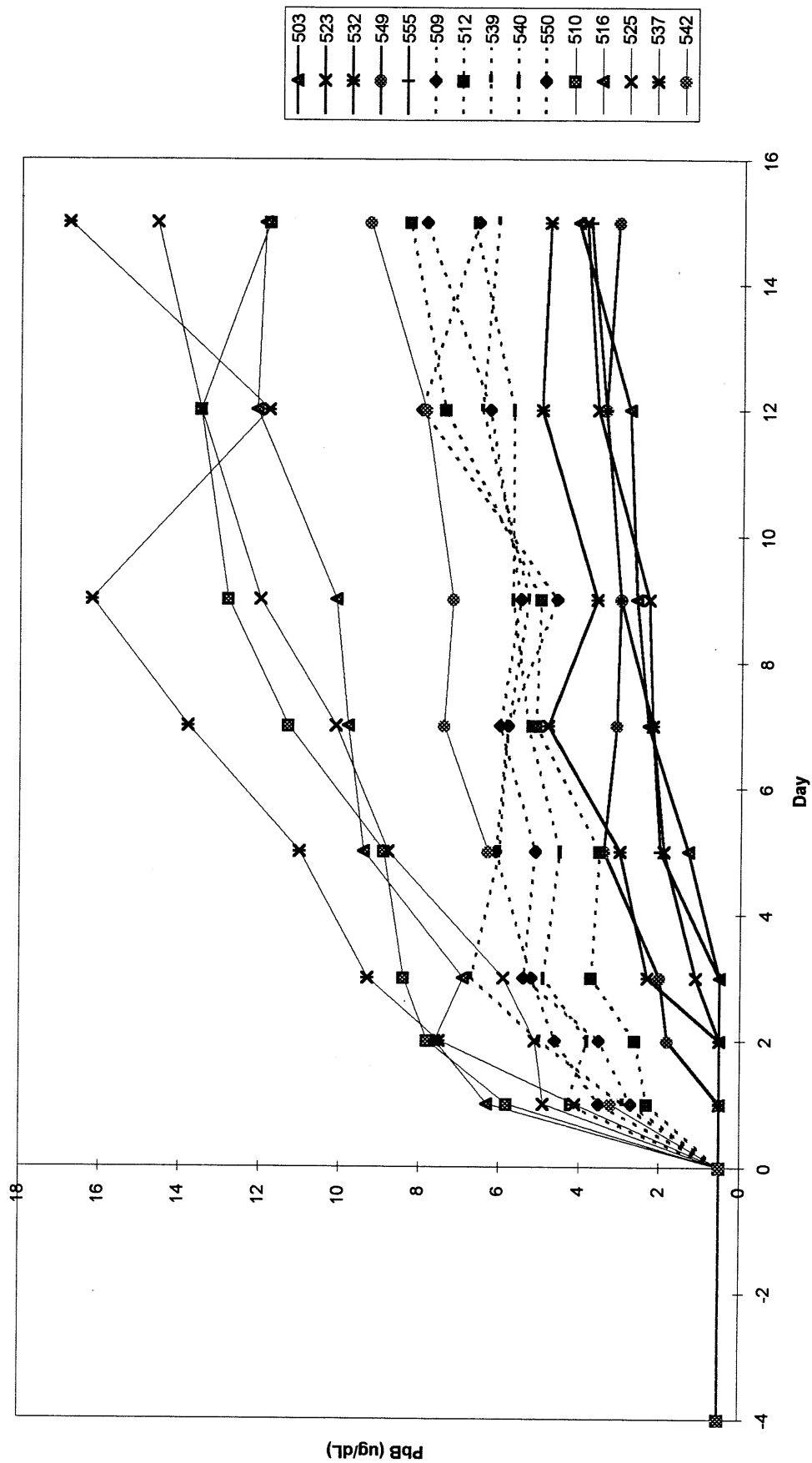
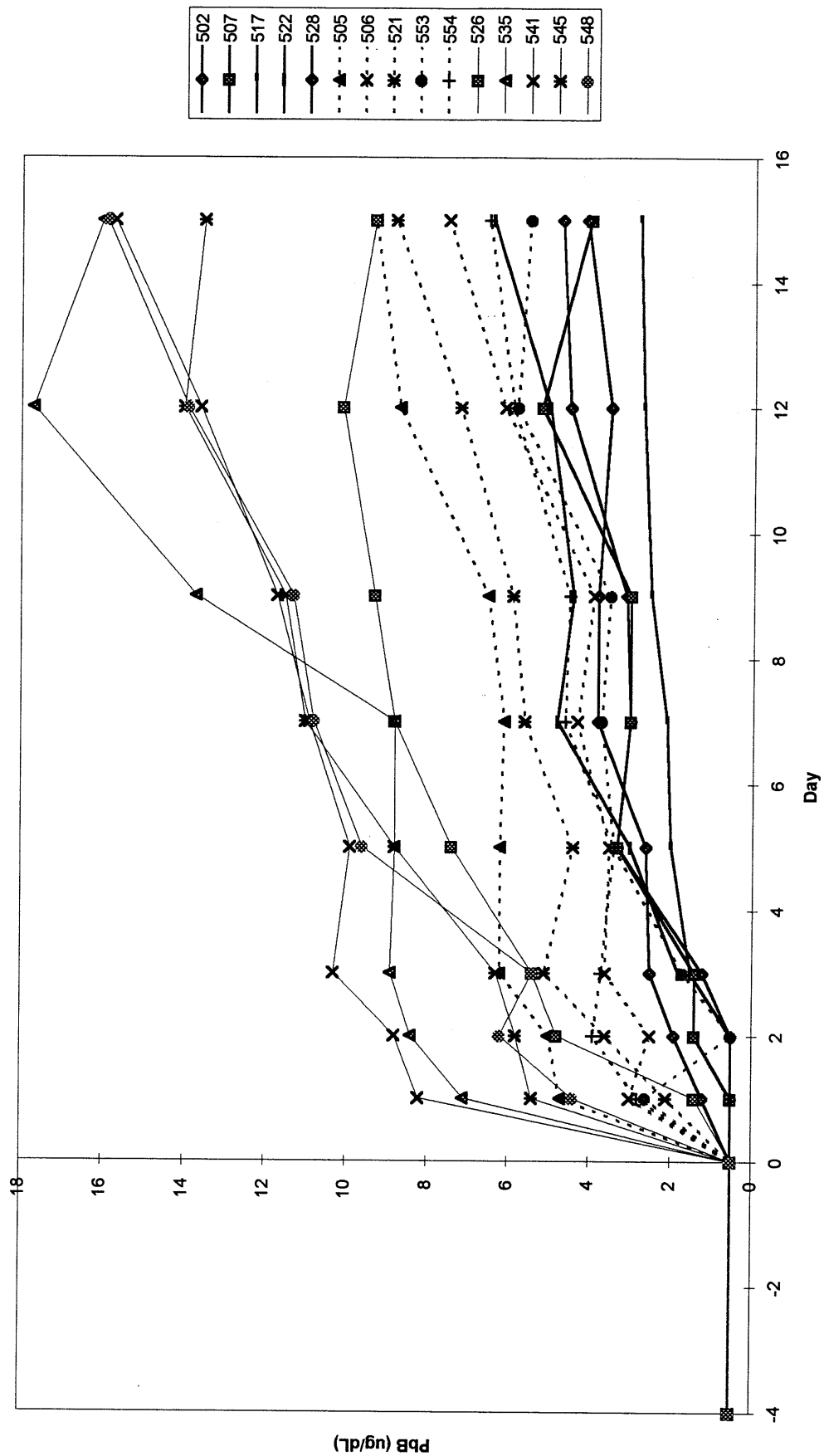


FIGURE A-2 Berm Groups by Day
Raw Data



**FIGURE A-3 Residential Groups
Raw Data**



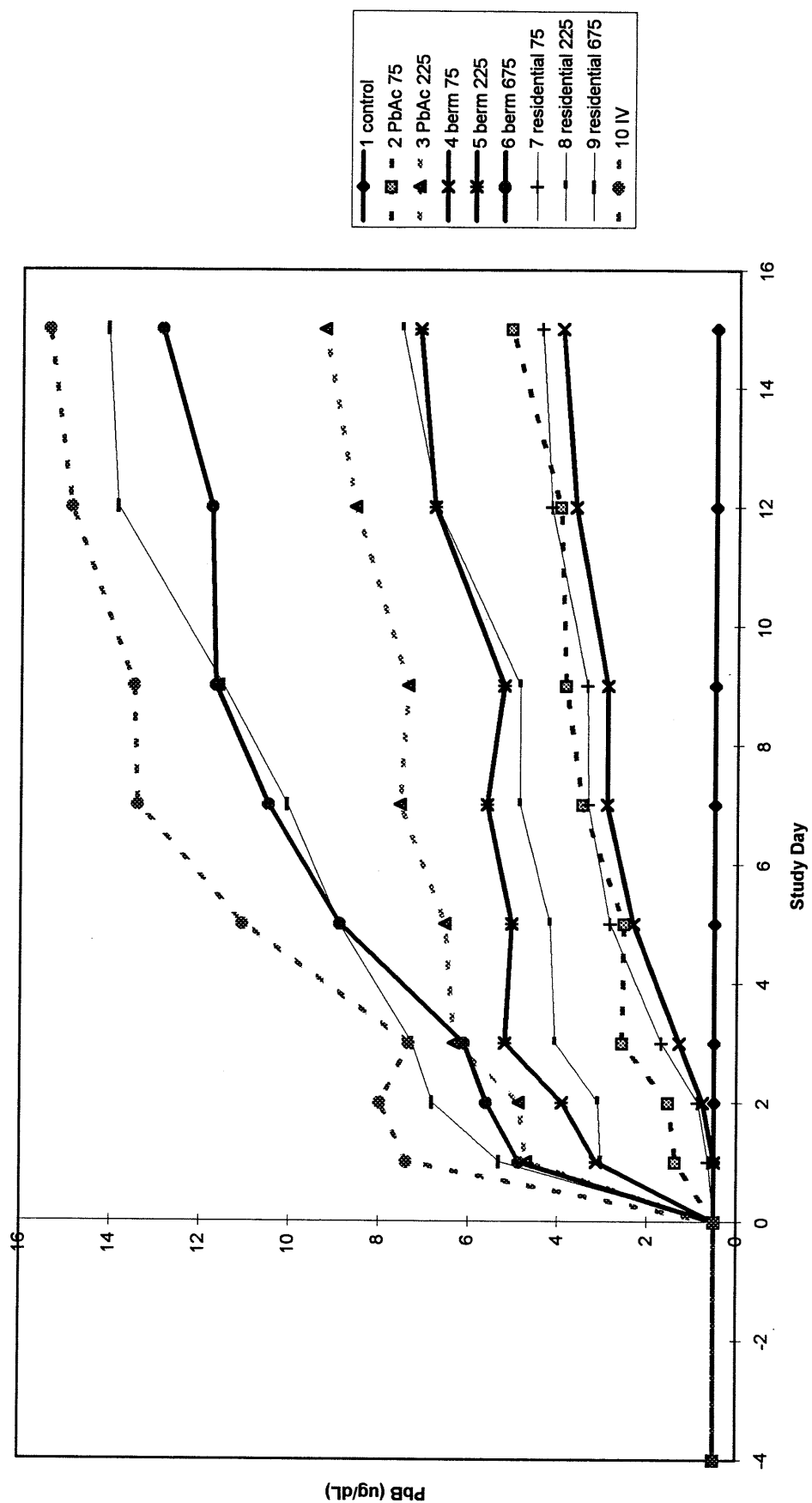
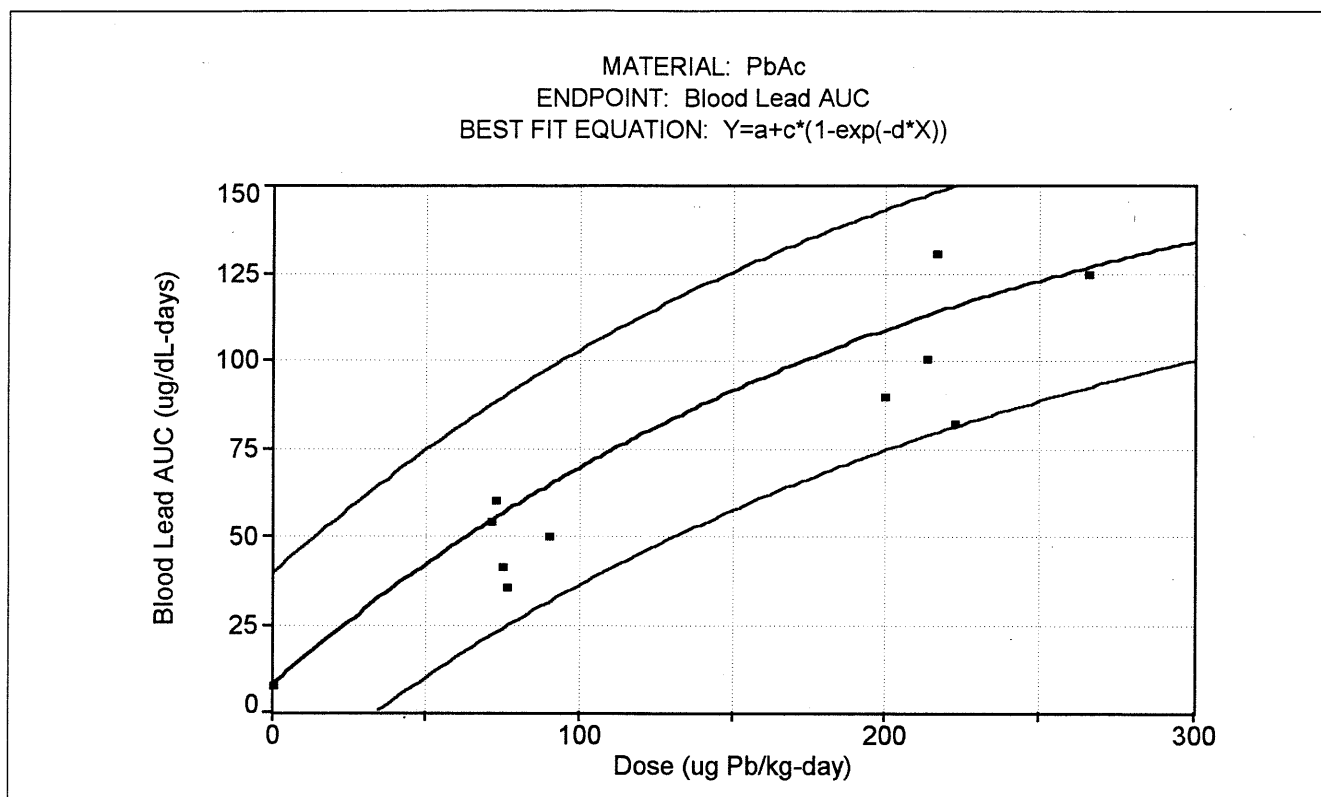


FIGURE A-5 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

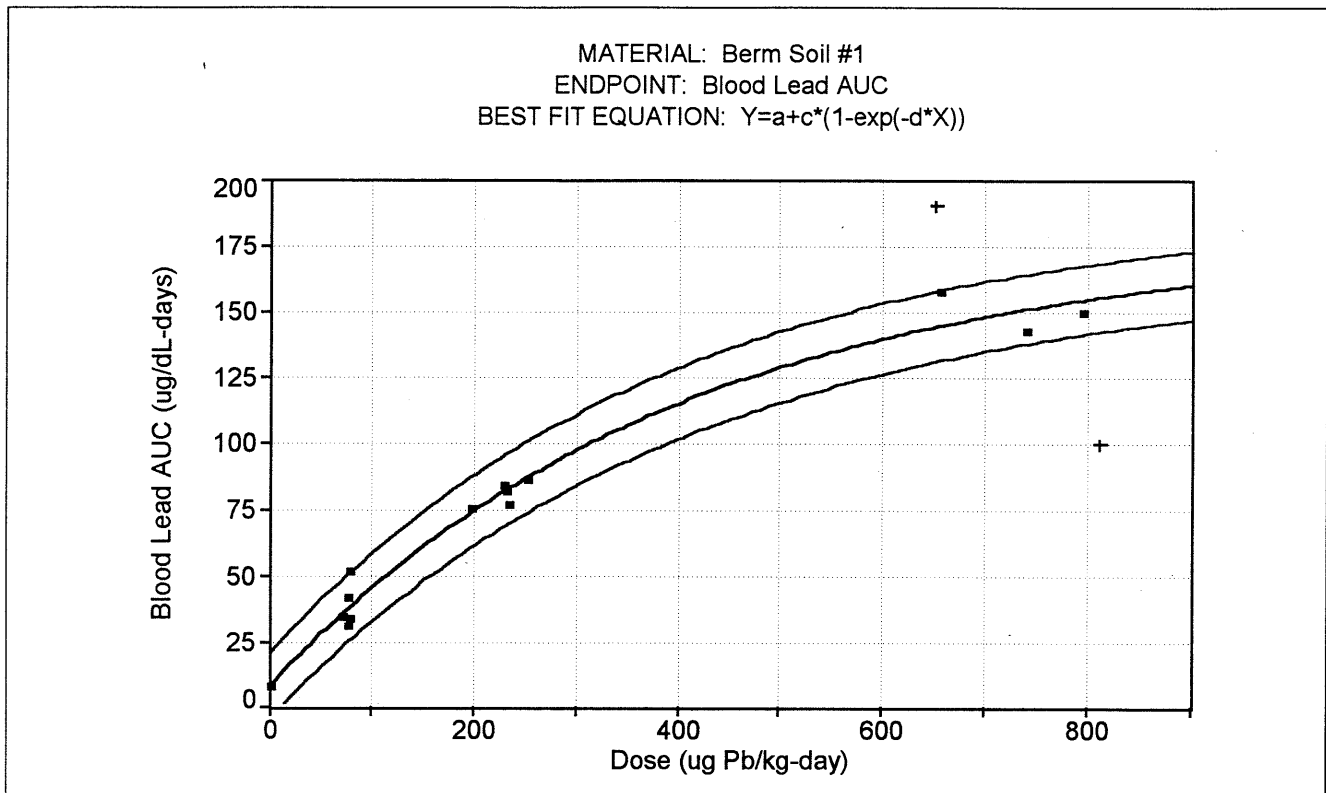


Parameters	Value	Std. Error	95% Confidence Limits	
a	7.57	fixed value	--	--
c	170.2	fixed value	--	--
d	0.0045	0.0004	0.0035	0.0055

Adj R ²	0.882
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-6 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

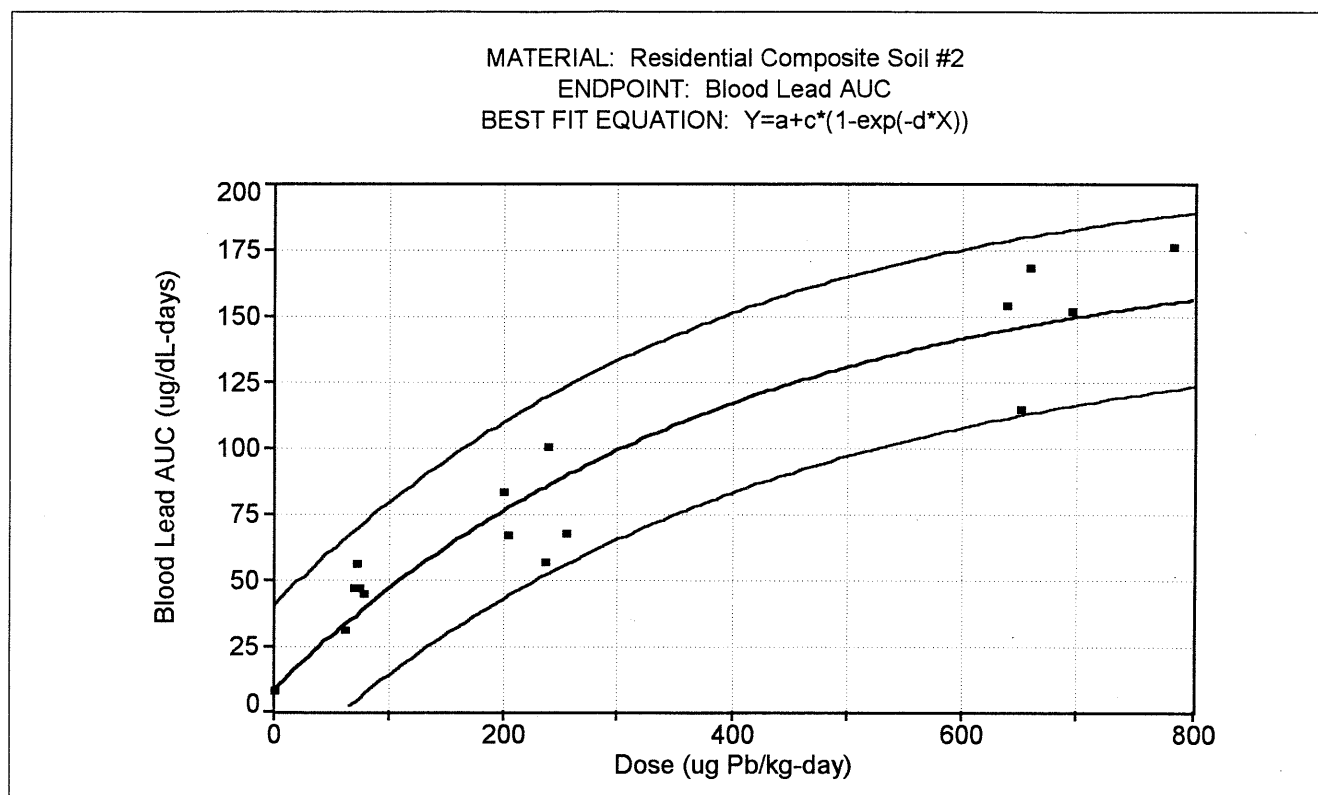


Parameters	Value	Std. Error	95% Confidence Limits	
a	7.57	fixed value	--	--
c	170.2	fixed value	--	--
d	0.0025	9.82E-05	0.0023	0.0027

Adj R ²	0.986
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-7 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

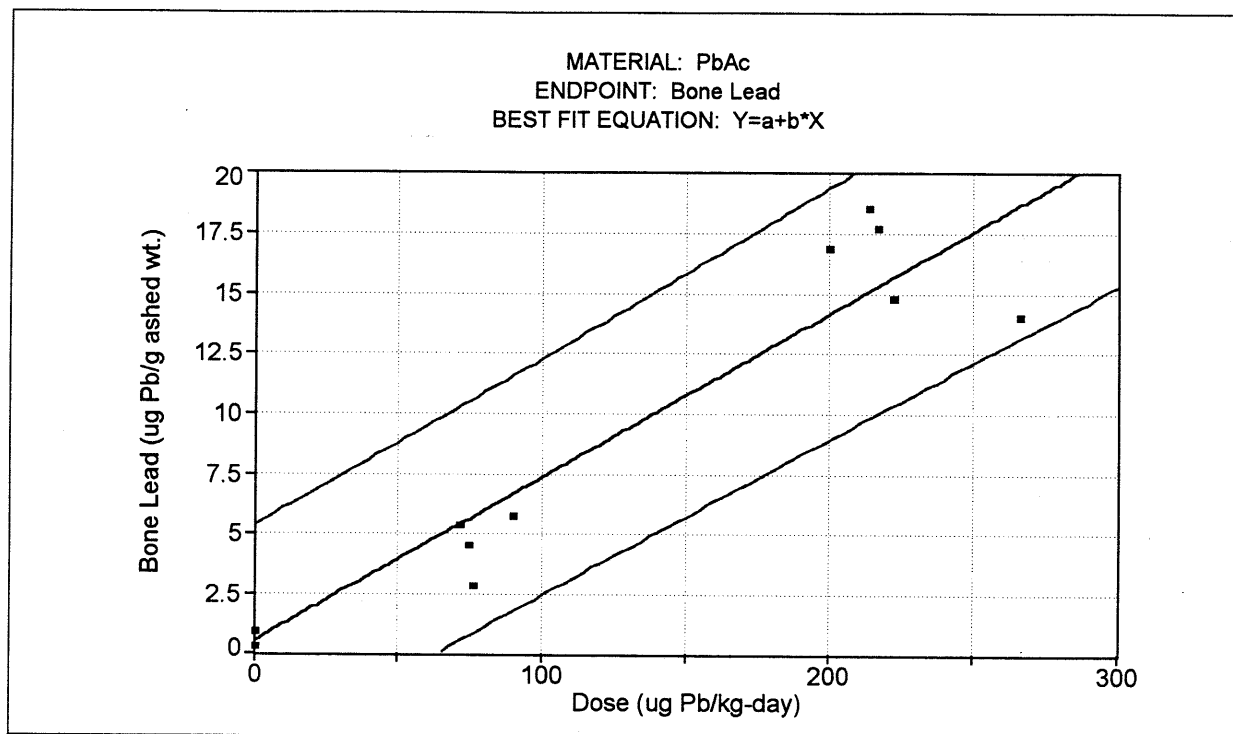


Parameters	Value	Std. Error	95% Confidence Limits	
a	7.57	fixed value	--	--
c	170.2	fixed value	--	--
d	0.0026	0.0002	0.0021	0.003

Adj R ²	0.925
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-8 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

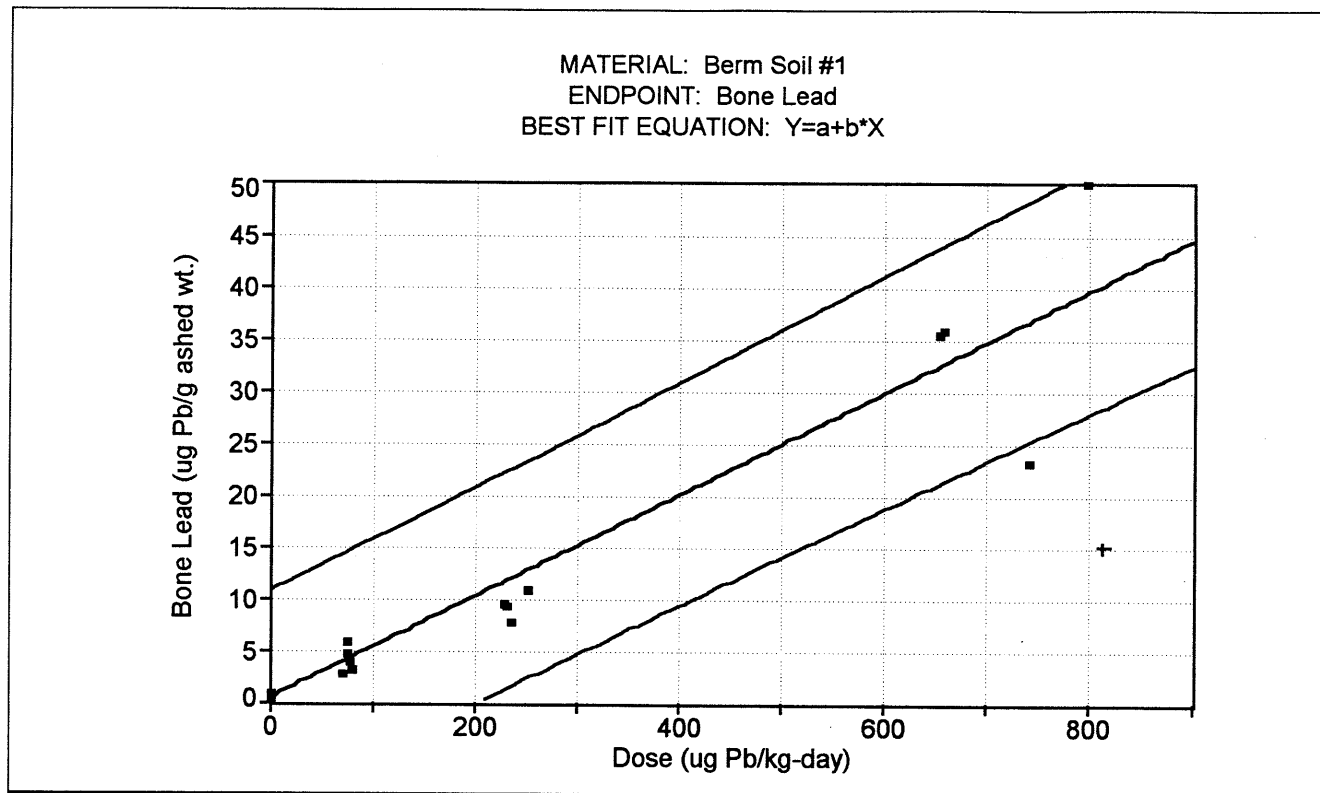


Parameters	Value	Std. Error	95% Confidence Limits	
a	0.494	fixed value	--	--
b	0.068	0.005	0.058	0.078

Adj R ²	0.905
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-9 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

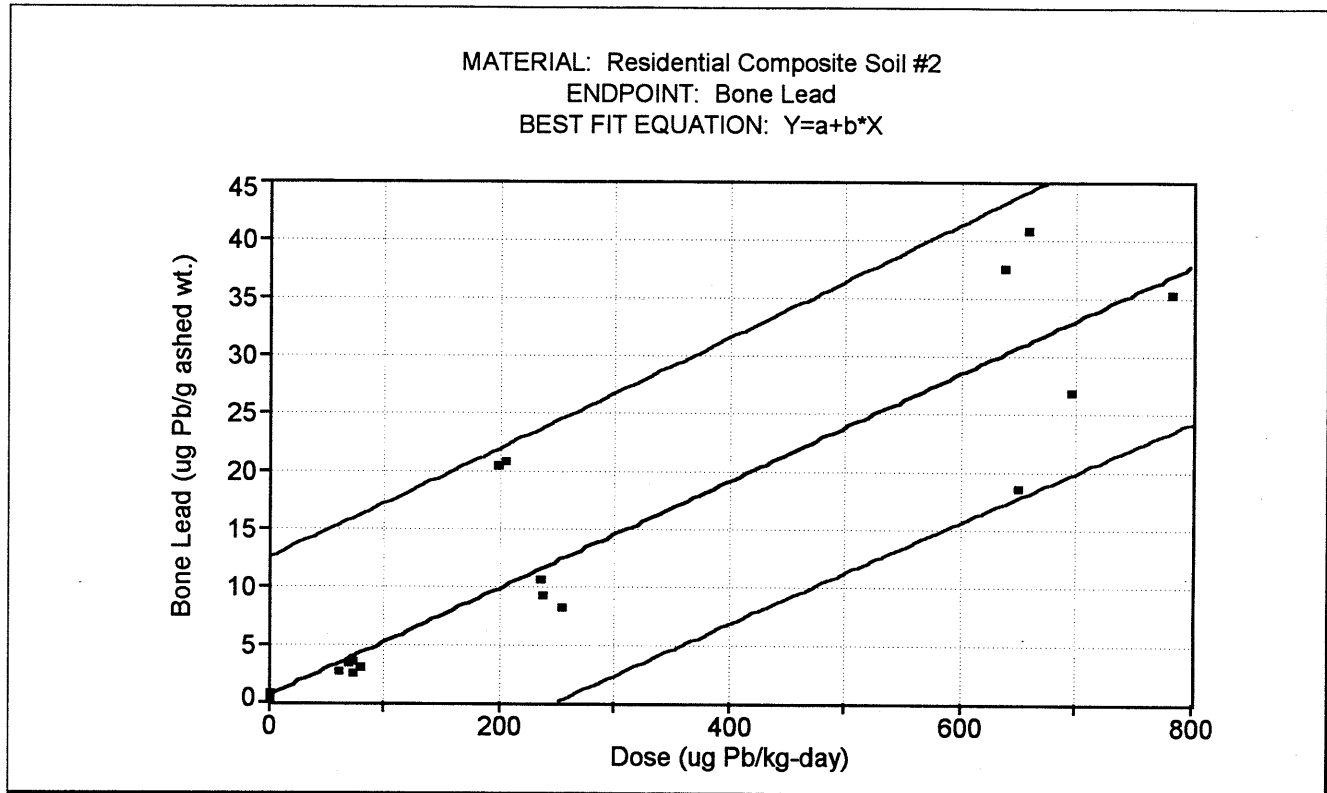


Parameters	Value	Std. Error	95% Confidence Limits	
a	0.494	fixed value	--	--
b	0.049	0.0033	0.0416	0.0559

Adj R ²	0.891
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-10 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

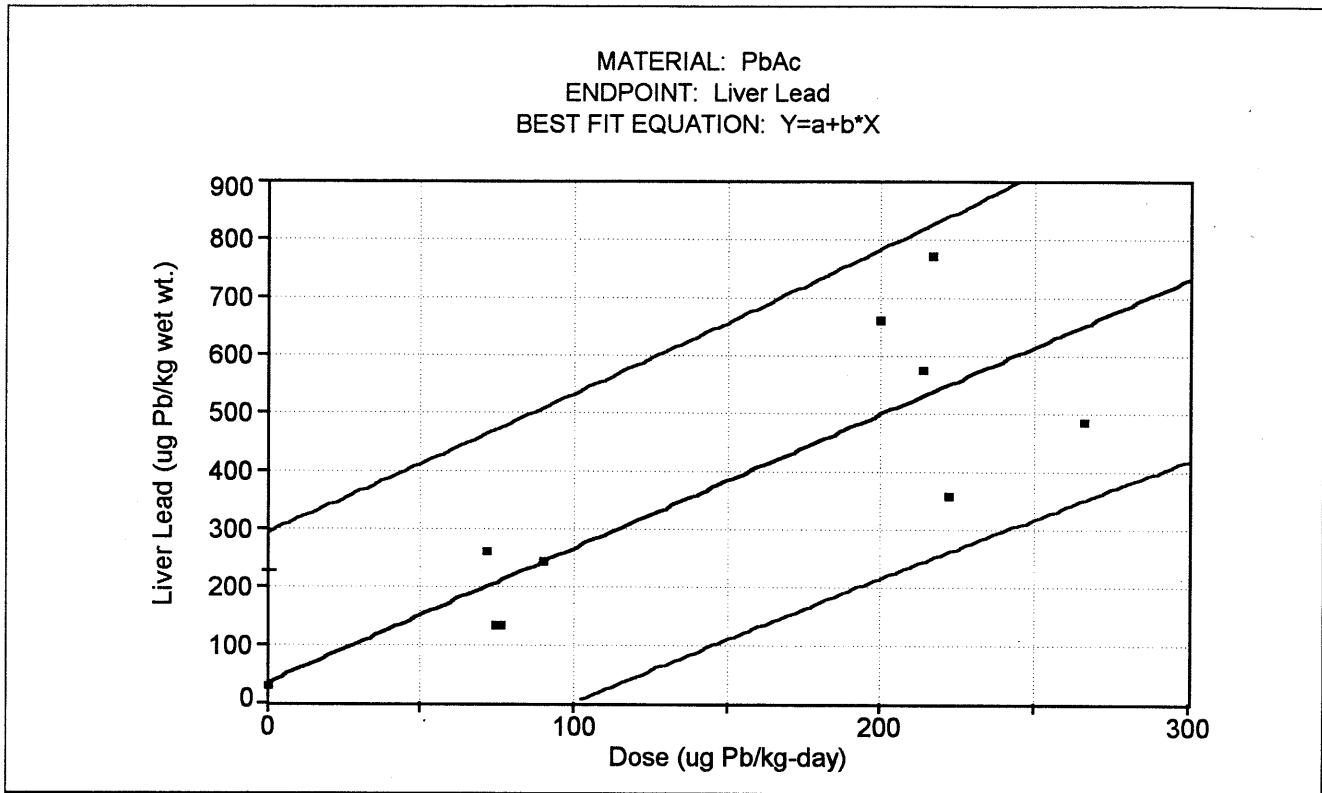


Parameters	Value	Std. Error	95% Confidence Limits	
a	0.494	fixed value	—	—
b	0.0464	0.0037	0.0384	0.0543

Adj R ²	0.819
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-11 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

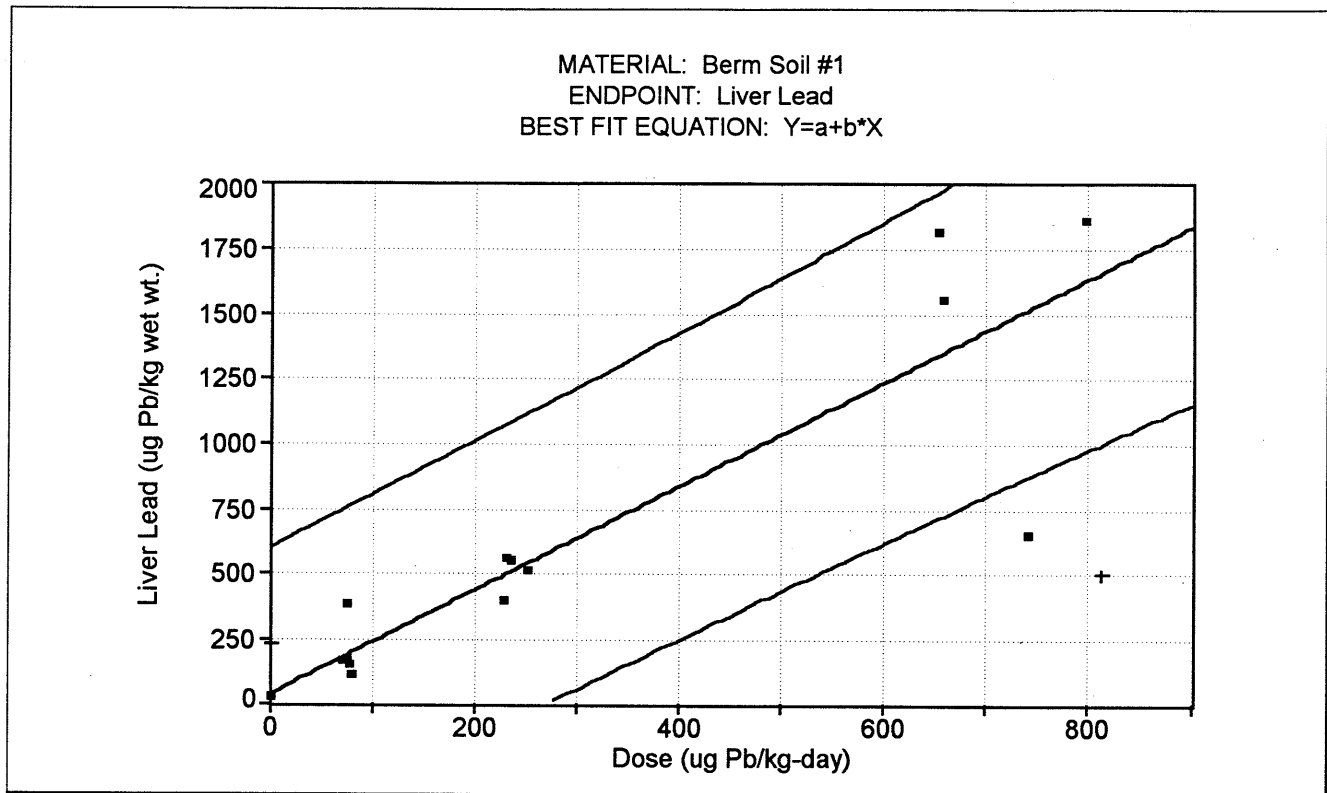


Parameters	Value	Std. Error	95% Confidence Limits	
a	33.04	fixed value	—	—
b	2.318	0.256	1.73	2.9

Adj R ²	0.788
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-12 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

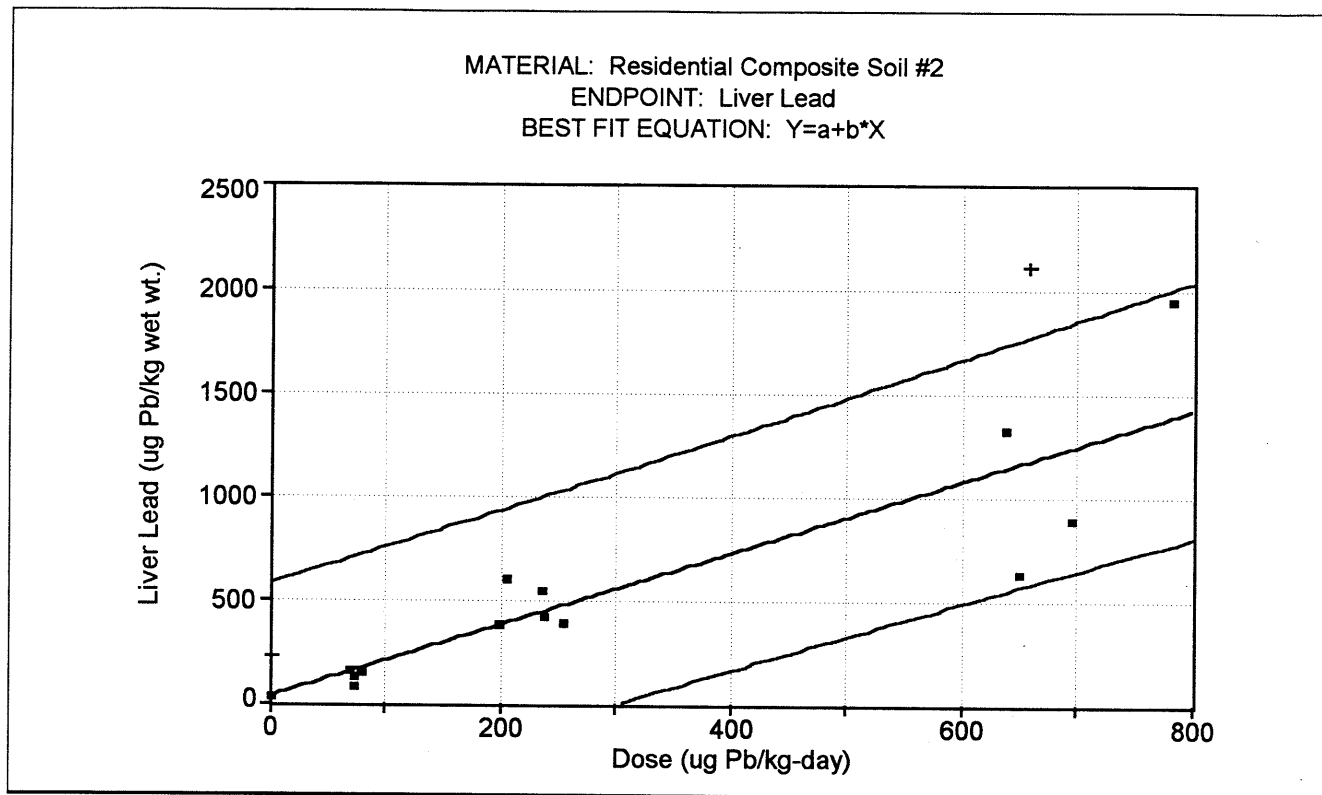


Parameters	Value	Std. Error	95% Confidence Limits	
a	33.04	fixed value	--	--
b	1.99	0.195	1.57	2.41

Adj R ²	0.806
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-13 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

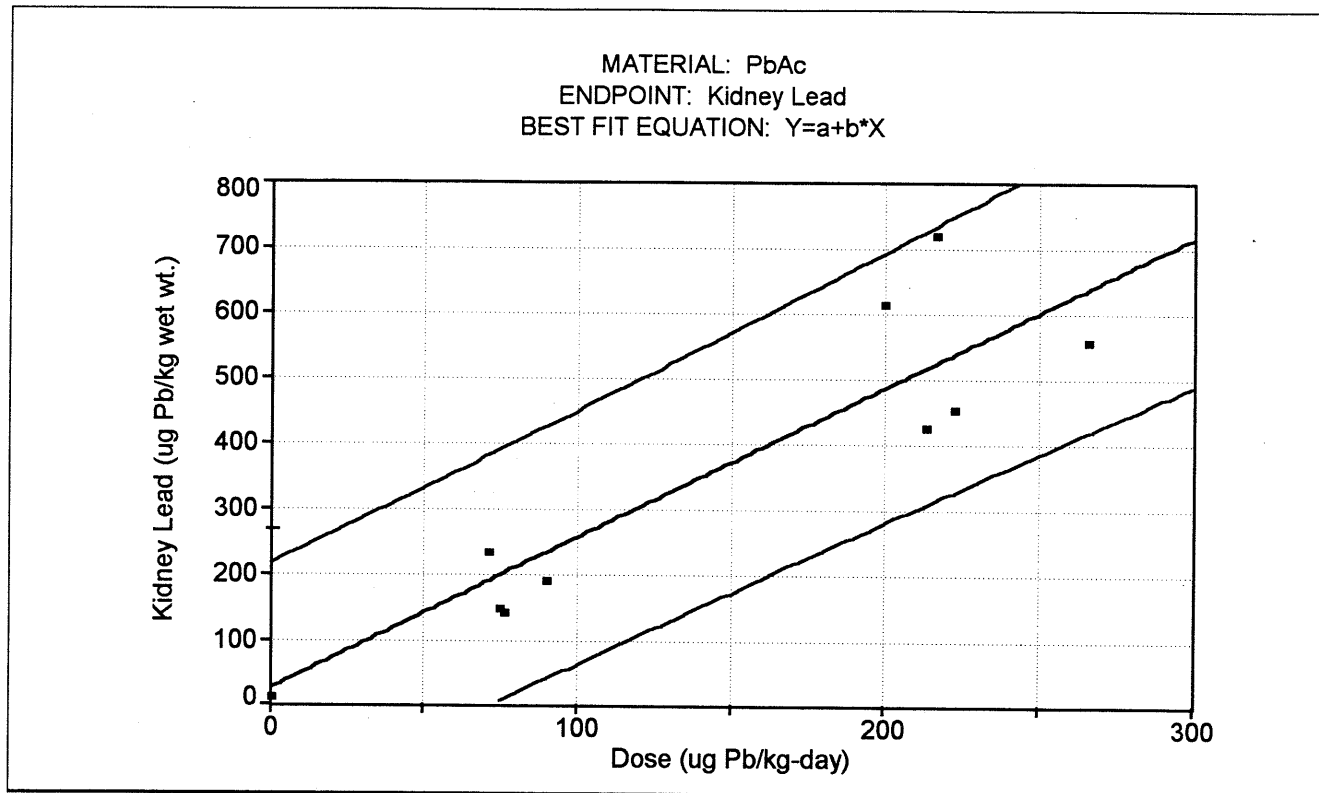


Parameters	Value	Std. Error	95% Confidence Limits	
a	33.04	fixed value	--	--
b	1.723	0.169	1.358	2.089

Adj R ²	0.76
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-14 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*

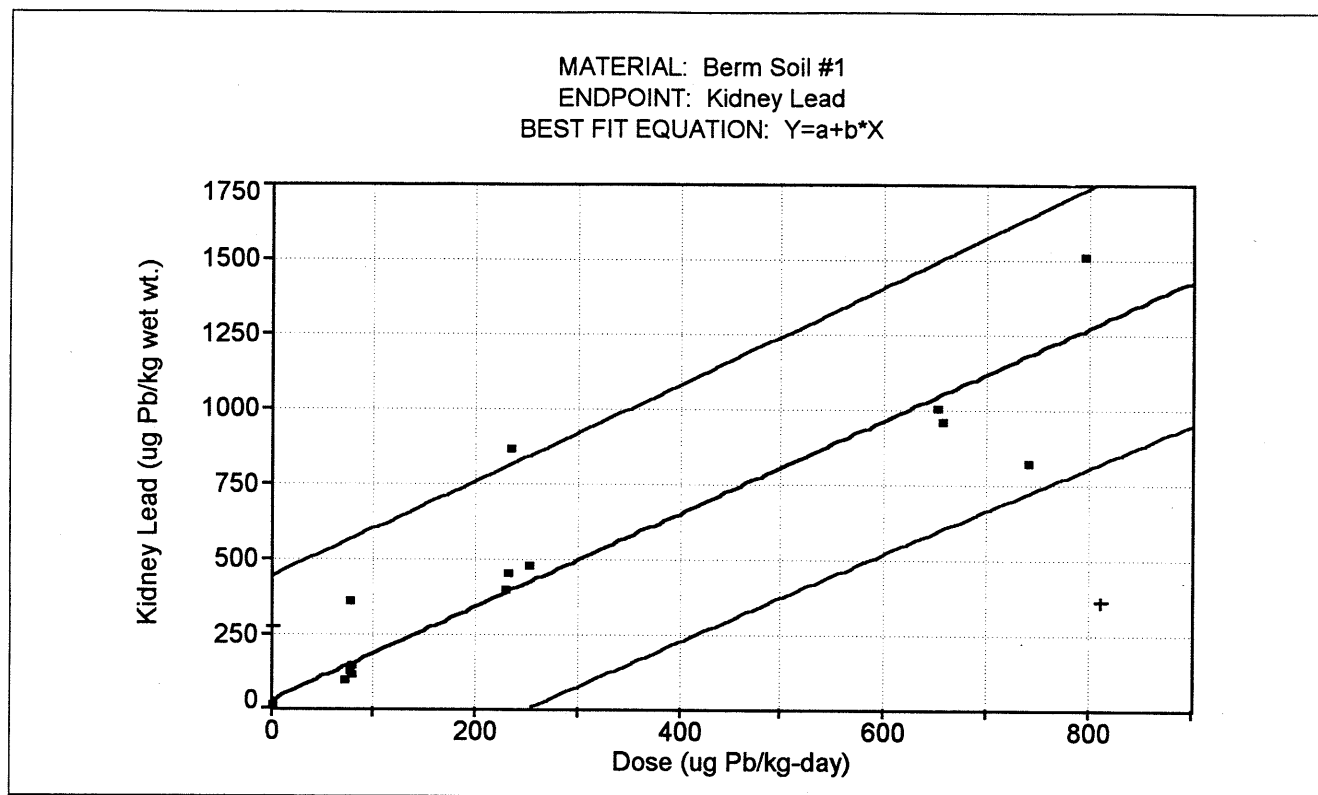


Parameters	Value	Std. Error	95% Confidence Limits	
a	23.5	fixed value	--	--
b	2.3	0.187	1.875	2.724

Adj R ²	0.882
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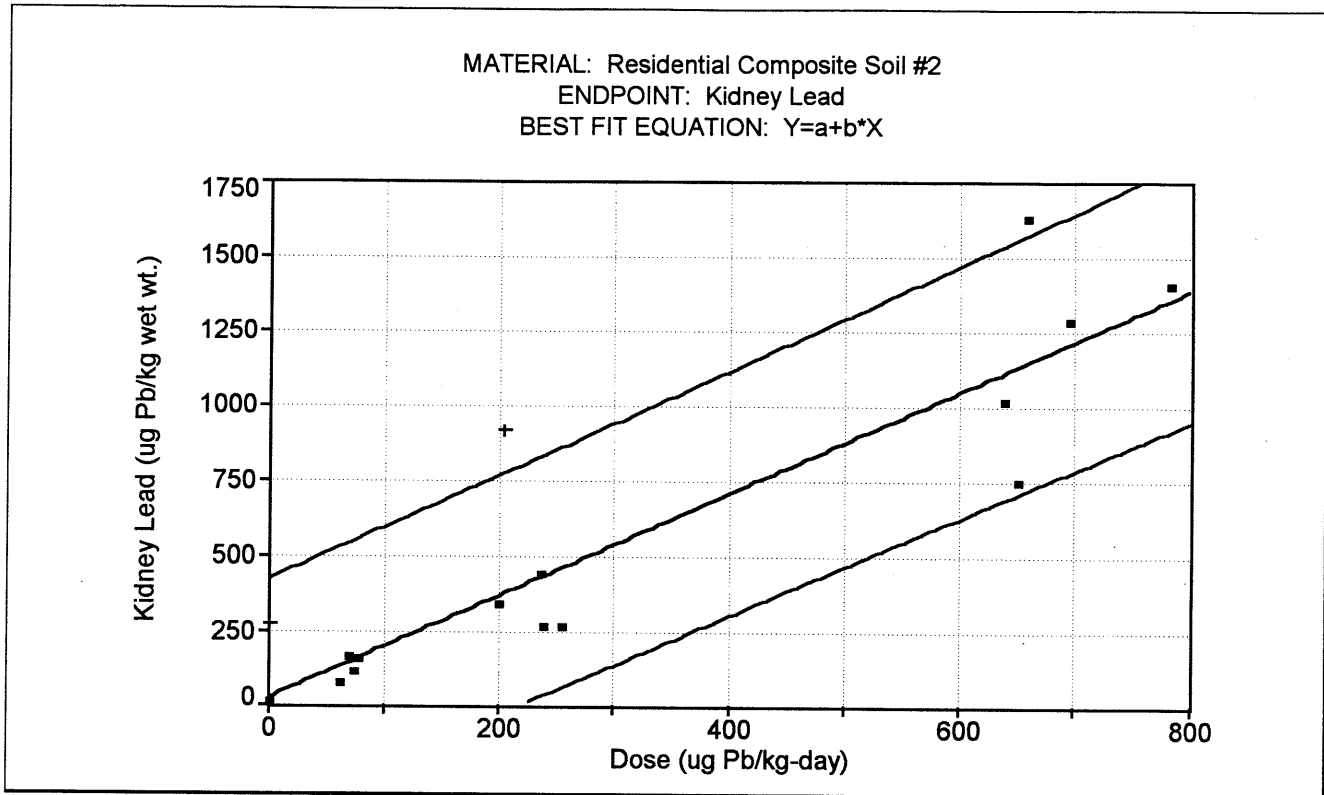
Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-15 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*



Generated using Table Curve 2D v. 3.0. Outliers represented by "+".

FIGURE A-16 BEST FIT CURVE WITH 95% PREDICTION INTERVALS*



Parameters	Value	Std. Error	95% Confidence Limits	
a	23.5	fixed value	--	--
b	1.698	0.114	1.453	1.943

Adj R ²	0.875
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Generated using Table Curve 2D v. 3.0. Outliers represented by "+".