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11.6 Confidential Site, Midwest, U.S.

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11.6.1 Site Description and Conceptual Site Model

The site is a mixed residential/commercial neighborhood in the Midwest. Historical industrial facilities operated in the area for approximately 50 years.

An in vitro bioaccessibility (IVBA) study for lead was conducted on site soil with the hope of observing lower relative bioavailability (RBA) than the USEPA default value of 60%. Given the large size of the neighborhood, the hope was that site-specific RBA data would allow calculation of a higher soil cleanup level than the default soil cleanup level (based on the default RBA). After considering the site-specific cleanup level calculations, the project manager decided not to use the site-specific cleanup levels, but to use USEPA's default residential cleanup level because of its precedence at other sites.

The focus of the study was to evaluate the oral bioavailability of lead in soil on numerous residential properties in an area that had been previously sampled for lead. The sample locations and depth intervals submitted for bioavailability testing were chosen to provide a range of lead concentrations.

A five-point composite of soil was collected at each of 31 residential locations (USEPA 2003c). The five-point composite was collected to be representative of the residential property as a whole (including soil from the front, back, and side yards of each property). Samples were collected from depths of 0 to 6 inches, 6 to 12 inches, or both, and were analyzed for total lead and bioaccessible lead. Of the samples collected, 19 samples were submitted for lead IVBA testing. Total lead concentrations in the samples submitted for IVBA testing ranged from 224 to 1249 mg/kg. The local background level of lead at the site was not established.

Information on soil type and soil chemistry was not provided. Exposure to site soils is due to residential land use.

11.6.2 Methodology Used for Evaluating Bioavailability

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Soils were prepared in the laboratory for analysis by sieving with a #60 sieve (250 µm grid size). This size fraction was chosen since this is the size of soil particles that are assumed to adhere to hands and be available for incidental ingestion.

Lead IVBA testing was performed using USEPA guidance (USEPA 2007b). Total lead data were obtained through analysis by SW3050/6010.

The laboratory cost for conducting the IVBA testing was approximately $1,900 (19 samples at $100 each).

Results of the IVBA study are shown in Table 11-4.

Table 11-4. Summary of IVBA results

Matrix	Sample Size [N]	IVBA [%]		
		Range	Mean	SD
Total soil	19	62.0 – 92.0	79.7	7.4
Surface soil (0 to 6 inches below ground surface [bgs])	13	73.0 – 92.0	82.1	6.2
Subsurface soil (6 to 12 inches bgs)	6	62.0 – 83.0	74.7	7.8

bgs – below ground surface
IVBA – in vitro bioaccessibility analysis
SD – standard deviation

Although the difference is small (<10%), the average IVBA of surface soil (0–6 inches bgs) was greater than that of subsurface soil (6–12 inches bgs). Because the IVBA ranges from surface and subsurface soil overlap and a significant difference does not appear to exist, the IVBA in the pooled dataset from surface soil and subsurface soil samples was used to

calculate a range of site-specific soil cleanup levels.

USEPA guidance (2007b) was used to calculate site-specific soil cleanup levels protective for children (up to 6 years old) at residential properties based on the use of site-specific IVBA data and USEPA's IEUBK model (USEPA 2010d).

11.6.2.1 Step 1—Estimation of In Vivo Relative Bioavailability *Read More*

The following empirical linear regression model was previously established by USEPA (2007b) between RBAs in vitro and in vivo (juvenile swine) procedures:

$$\mathrm{RBA} = 0.878 \times \mathrm{IVBA} - 0.028$$

Using this equation, the in vivo RBA of lead in site soil was estimated based on the site-specific IVBAs measured in soil samples collected from the site. A range of site-specific RBAs corresponding to the minimum, average, and maximum was calculated. The sample-specific RBAs range from 51.6% to 78.0%, with an average RBA of 67.2%. The RBA based on the average IVBA is approximately 7% higher than USEPA's default RBA of 60% used in the IEUBK model.

The average RBA in the pooled dataset from surface soil and subsurface soil samples was used to calculate soil cleanup levels.

11.6.2.2 Step 2—Absolute Bioavailability *Read More*

Based on available information in literature on lead absorption in humans, USEPA estimates that the absolute bioavailability of lead from water and the diet is usually about 50% in children (USEPA 2010d). Thus, when a reliable site-specific RBA value for soil is available, it may be used to estimate a site-specific absolute bioavailability in that soil, as follows:

$$\mathrm{ABA}_{\mathrm{soil}} = 50\% \cdot \mathrm{RBA}_{\mathrm{soil}}$$

Where:

$$\mathrm{ABA}_{\mathrm{soil}} = \text{ABA of lead in site soil ingested by a child}$$

$$\mathrm{RBA}_{\mathrm{soil}} = \text{site-specific RBA of lead}$$

The calculated ABA_{soil} for the site ranges from 25.8% to 39.0%, with an average ABA_{soil} of 33.6%. The calculated ABA_{soil} based on the average RBA is approximately 4% greater than USEPA's default ABA of 30% used in the IEUBK model.

11.6.2.3 Step 3—Calculation of Cleanup Levels *Read More*

The estimated site-specific ABA_{soil} was used in the IEUBK model to calculate a soil cleanup level corresponding to the USEPA target level of 95% of the population with a blood lead level (BLL) below 10 micrograms per deciliter (µg/dL). The site-specific ABA_{soil} value replaced the IEUBK model default soil and dust GI bioavailability values. The remaining default input values were left unchanged in the IEUBK model.

The "multiple runs" option was used to obtain percentages of the population with a BLL above 10 µg/dL for a range of soil lead concentrations using the minimum, maximum, and average site-specific ABA_{soil}. Based on the model output, the soil cleanup levels corresponding to the target BLL range from 306 mg/kg (based on the maximum IVBA) to 467 mg/kg (based on the minimum IVBA), with 357 mg/kg as the average.

11.6.3 Application of Bioavailability to Risk Assessment and Effect on Site Decisions

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This lead bioavailability study was performed to develop site-specific soil cleanup levels for lead. Nineteen soil samples were collected from the site for IVBA analysis. The calculated site-specific soil cleanup level range was 306 to 467 mg/kg.

After considering several factors, including maintaining national consistency, USEPA decided to use its default residential soil cleanup level of 400 mg/kg. Community outreach on this site included public meetings where the topic of bioavailability was discussed.