LeadSpread 9- INFORMATION FOR USERS

California Department of Toxic Substances Control (DTSC)

Human and Ecological Risk Office (HERO)

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LeadSpread 9

A tool for evaluating exposure and the potential for adverse health effects resulting from childhood and adult exposure to lead in the environment.

LeadSpread was created to run on Microsoft Excel®

1) Background:

Historically, LeadSpread has been a tool used by DTSC to estimate blood lead concentrations resulting from exposure to lead in soil at contaminated properties. Exposures via the ingestion, inhalation and dermal pathways are represented by equations relating an increase in incremental blood lead concentration to the soil lead concentration at a contaminated site to provide an estimate of the median blood lead concentration of a receptor exposed to lead contaminated soils. Upper percentile blood lead concentrations, ninetieth (90th) to ninety-fifth (95th), are estimated from the median value by assuming a log-normal distribution with a geometric standard deviation (GSD) of 1.6 (US EPA, 1994 and White et. al., 1998).

The toxicity criterion on which Leadspread 9 is based, is CalEPA's Office of Environmental Health Hazard Assessment's (OEHHA) 2007 toxicity evaluation of lead with a source-specific "benchmark change" in blood lead concentration of 1 microgram/deciliter (µg/dL). One µg/dL is the estimated incremental increase in children's blood lead that would reduce IQ by up to 1 point. Two key exposure parameters utilized in LeadSpread have been updated since the previous version of LeadSpread (LeadSpread 8) was developed. The two key exposure parameters are **soil ingestion rate and bioavailability** of ingested lead. These revised values will be discussed in a later section below. Values for inhalation rate and body surface area, which have a lesser effect on blood lead levels have also changed since the publication of LeadSpread 8 and are updated in LeadSpread 9.

2) General Information for LeadSpread 9:

LeadSpread 9, 2022 runs using Microsoft Excel. The single worksheet of the Excel workbook is a revision of LeadSpread 8 and should be used for evaluating residential or industrial land use scenarios. Unlike LeadSpread 8, LeadSpread 9 does not include a separate worksheet for evaluating adult exposure scenarios. LeadSpread 8 utilized DTSC's version of US EPA's Adult Lead Model on a separate worksheet for calculation of the adult industrial and residential exposure scenarios. In LeadSpread 9, the residential child, residential adult and adult industrial scenarios are all available on the same worksheet and the child and adult calculations are all implemented within the LeadSpread 9 computational format. The basic equations and majority of default input values in the LeadSpread 9 Worksheet 1 are similar to previous versions. Information on updates and other model inputs in this 2022 revision of DTSC's LeadSpread model are described below:

a) Soil Ingestion

Soil Ingestion – Child. For exposure parameters, LeadSpread 9 uses central tendency values. The 50th, 90th, and 95th percentile values for blood lead are estimated by assuming a log-normal distribution of blood lead with a Geometric Standard Deviation of 1.6. The soil ingestion pathway plays a major role in determining the blood lead output in all versions of LeadSpread. The soil ingestion value for children utilized in DTSC's LeadSpread 8 model is 100 mg/day. This was US EPA's recommended central tendency value for soil ingestion when LeadSpread 8 was issued in 2011. A 2017 update to the US EPA Exposure Factors Handbook (US EPA, 2017) lists soil plus dust ingestion values for seven age ranges from 0 to <6 months up to 12 years to adult. The range of 1 to 6 years is the most appropriate range for estimating children's lead exposure because they have a high soil ingestion rate and have the highest soil ingestion to body weight ratio. US EPA chose an updated central tendency value of 80 mg/day for this age range (US EPA, 2017). The value was selected by taking the average from three separate methods of estimating soil ingestion (tracer, biokinetic modeling and activity modeling). Values for each of those methods was obtained by averaging values from individual studies utilizing the specific method. In the tracer methodology, levels of elements (tracers) in children's feces and urine are quantitated and compared to levels of the tracers in soil and dust in areas such as backyards where children have their primary soil exposure. Exposure from other sources of the tracers such as water and food are also taken into account in the estimates. Aluminum, silicon, and titanium are the tracers most commonly used. For the tracer method, US EPA utilized four studies as analyzed by Stanek and Calabrese (1995a). Mean estimated daily soil ingestion values obtained from the four studies were 132 mg/day, 69 mg/day, 66 mg/day and 129 mg/day, giving an average value of 99 mg/day.

The biokinetic modeling method utilizes US EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model of lead exposure. Measured values of lead in the test population's blood as well as lead levels in soil, food, water, and other sources of lead in the test population are input into the model and an estimate of soil and dust ingestion of the test population is obtained. The soil ingestion estimate from the biokinetic modeling method was based on two studies. One with a value of 113 mg/day (Hogan et. al.,

1998) and the other 67 mg/day (Von Lindern et.al., 2016) giving a mean value of 90 mg/day.

The activity modeling method is based on observational studies of children's hand to mouth and object to mouth activity, combined with studies of soil and dust adherence to hands and objects and removal efficiency of soil and dust by saliva. The activity modeling estimate for the soil ingestion method was based on two separate studies with averages of 61 mg/day (Wilson et. al. 2013) and 68 mg/day (Ozkaynak et. al. 2011) giving a mean value of 65 mg/day.

US EPA averaged the results from all three methods rounding down to yield a value of 80 mg/day for a child of one to six years of age. This value is used in LeadSpread 9, as it is the most recent scientifically based value issued by US EPA.

Soil Ingestion – Adult. The adult soil ingestion value utilized in LeadSpread 8 was 50 mg/day. This was US EPA's recommended central tendency value for soil ingestion by adults when LeadSpread 8 was issued in 2011. The 2017 update to US EPA's Exposure Factors Handbook identified 30 mg/day as the soil plus house dust ingestion for an adult (US EPA, 2017). The value was selected by taking the average from two separate methods of estimating soil ingestion (tracer and activity modeling). For the activity modeling study, US EPA estimated an average value of 4 mg/day for the age range of from 12 years to 60 years of age and older (Wilson et. al. 2013). A mean soil plus house dust ingestion value of 52 mg/day was measured in a tracer study of 33 adults (17 males and 16 females) using silicon and aluminum as tracers (Davis and Mirick, 2006). US EPA averaged the results from the two methods which gave a value of 28 mg/day. US EPA rounded that value up to 30 mg/day. We selected this value for LeadSpread 9 as it is the most recent scientifically based value issued by US EPA.

b) Bioavailability.

In LeadSpread, bioavailability refers to the fraction of lead from ingested soil that is absorbed from the gastrointestinal tract. LeadSpread utilizes relative bioavailability (RBA), the fraction of ingested lead in soil that is absorbed from a site as compared to the fraction of lead absorbed from a lead acetate solution. The bioavailability of lead in ingested soil has a direct effect on how much of the ingested lead is transported to the blood. A change in the bioavailability parameter will have a direct effect on the estimated blood lead predicted by LeadSpread. The value for bioavailability used in LeadSpread 8 was 0.44 (44%). This value dates from the original LeadSpread model and is based on a 1990 study in rats looking at the oral absorption of lead in soil as compared to absorption of lead from an orally administered dose of a solution of lead acetate. Bioaccessibility of lead is determined by analyzing for the fraction of lead from a soil sample that is present in solution after being subjected to an *in vitro* extraction procedure which mimics conditions in the human gastrointestinal tract. These studies are considered a valid substitute for animal studies, and they are simpler and cheaper than bioavailability studies in animals. The bioaccessible fraction can be converted to the bioavailable fraction by applying a small adjustment factor (US EPA, 2007).

Currently, US EPA does not have a default bioavailability or bioaccessibility for lead. The Toxicological Profile on Lead (ATSDR, 2020) estimated a mean soil ingestion bioavailability of lead in soil of 60%. This value is based on studies of 33 different soils. The US EPA Integrated Science Assessment for Lead (2013) looked at soils obtained from 11 hazardous waste sites. Lead RBA estimates were made using the *in vitro* bioavailability assay, a total of 270 estimates were made of lead RBAs. The mean for the site-wide RBA estimates (n = 11 sites) was 0.57 (SD 0.15), median was 0.63, and 5th to 95th percentile range was 0.34 to 0.71. US EPA Region 8 (2020) has issued a document stating, "*The default value used in the IEUBK model for the relative bioavailability of lead in soil is 60 percent (EPA 1994). That is, it is assumed that lead in soil is absorbed about 60 percent as well as soluble lead that is ingested in water. When risk calculations based on the default RBA for lead are close to (either above or below) a level of health concern, then acquisition of site-specific data may be needed to help increase the accuracy of the assessment.*" It should be noted that studies have shown a wide variation in the bioavailability/ bioaccessibility of lead. Based on the above, 60% or 0.60 is selected as the default RBA to be used in LeadSpread 9. With prior DTSC oversight, guidance, and approval, Responsible Parties may use a U.S. EPA approved *in vitro* assay, with adjustment factor applied, to measure the RBA of lead at their site.

c) Inhalation rate.

LeadSpread 8 specifies 6.8 m^3/day as the inhalation rate for a child. HERO's Human Health Risk Assessment (HHRA) Note 1 (DTSC, 2019) and US EPA currently recommend 10 m^3/day as a child's inhalation rate. The air pathway plays only a minor role in LeadSpread and in most of the lead exposure scenarios HERO encounters. In LeadSpread, the air pathway only accounts for site related soil that is re-suspended into the breathing zone by wind. Despite the large difference between 6.8 and 10 m^3/day, substituting 10 for 6.8 m^3/day for the inhalation rate parameter in LeadSpread has a negligible effect on the predicted blood lead. HERO specifies 10 m^3/day for the child inhalation rate in LeadSpread 9 for consistency with current recommended values by both DTSC and US EPA. The adult residential value is 20 m^3/day and the adult industrial value is 14 m^3/day (DTSC, 2019).

d) Skin Surface Area.

LeadSpread 8 (2011) uses 2900 cm^2 as a skin surface area for a child. HERO's HHRA Note 1 and US EPA currently recommend 2373 cm^2 for a child's skin surface area. As with the inhalation pathway, the dermal absorption pathway plays only a minor role in LeadSpread and substitution of 2373 cm^2 for 2900 cm^2 has a negligible effect on estimated blood lead. HERO uses the current recommended value of a child's skin surface area in LeadSpread 9. In accordance with HHRA Note 1, the residential adult value skin surface area of 6032 cm^2 is used for both the residential and the industrial exposure scenarios in LeadSpread 9.

e) Geometric Standard Deviation.

A Geometric Standard Deviation of 1.6 is used in LeadSpread 9. The same value of 1.6 was used in LeadSpread 8 for the residential child. It is based on a study of blood lead measured in children residing near toxic waste sites with lead contamination (US EPA, 1994 and White et. al., 1998).

LeadSpread 8 uses a GSD of 1.8 for the adult. In LeadSpread 9, the adult calculations are included in the same worksheet as the child rather than a separate worksheet as in LeadSpread 8. A value of 1.6 was selected for the adult in LeadSpread 9, the same as the child. A GSD of 1.6 was selected because the LeadSpread model for the adult (and child) estimates only an incremental increase, not total blood lead concentration. The incremental increase includes only blood lead resulting from on-site exposures, not all lead sources such as drinking water and diet. This results in less variability in blood lead concentrations and justifies the smaller GSD of 1.6.

f) Ingestion Constant (adult).

The value of 0.09 (µg/dL)/µg/day) was obtained from "Recommendation of the Technical Review Workgroup (TRW) for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil (U.S. EPA, January 2003)." The document utilized a published 1983 study by Pocock et. al. of blood lead versus tap water with over 900 participants.

g) Fetal/Maternal Blood Ratio.

In the adult scenarios for LeadSpread 9, OEHHA's Benchmark dose of 1 µg/dl is applied to a fetus carried by an exposed adult woman. LeadSpread estimates the blood lead concentration of the adult receptor and the dose to the fetus is calculated by multiplying the adult blood lead by the fetal/ maternal blood ratio to estimate the fetal blood lead. The US EPA identified the fetal/maternal blood ratio as 0.9 for use in the EPA's Adult Lead Model (US EPA, 2003). This value is used in the adult scenarios in LeadSpread 9 to estimate the Blood Lead Level of a fetus carried by an adult woman in the adult scenarios in LeadSpread 9.

h) Blood Lead Level of Concern.

In the development of LeadSpread 8, the blood lead level increase that is of concern was updated to 1 µg/dL based on the 2007 Cal/EPA OEHHA benchmark incremental change criterion for lead (California EPA, 2007). This is continued in LeadSpread 9. Previous versions of LeadSpread (LeadSpread 7 and below) calculated Preliminary Remediation Goals (PRGs) which were the concentrations in exterior soil and interior dust that result in a 95th and 99th percentile estimate of blood lead equal to 10 µg/dL. Since the target blood lead level of concern was updated to the health-protective criterion of 1 µg/dL in LeadSpread 8, HERO considers the 90th percentile of the distribution appropriate for use in calculating a lead soil PRG.

i) Exposure Routes.

The LeadSpread 9, Worksheet evaluates a source-specific exposure to lead in soil assuming the following exposure routes: ingestion of indoor dust and outdoor soil, dermal contact with soil and inhalation of soil originating from the site, being suspended into the breathing zone. For site-related exposures to lead in media other than soil (e.g., water or air) or if the home-grown produce pathway is anticipated at the site, the DTSC toxicologist assigned to the site should be contacted.

j) Background Exposures.

Since the OEHHA benchmark dose is an incremental dose resulting from exposure to site related soil only, exposures from sources other than soil from the site are not evaluated in LeadSpread 9. For background exposures to lead in media other than soil (e.g., water or air from offsite sources) the DTSC toxicologist assigned to the site should be contacted.

k) Alternate Land Use Scenarios.
For land use scenarios where adult exposure pathways may need to be adjusted from what is provided in LeadSpread 9, the DTSC toxicologist assigned to the site should be contacted.

l) Worksheet notes.
Many of the Worksheet cells contain notes which explain the cell contents when the cursor is moved over the cell. References are provided in comments attached to the Worksheet cell A27. For reference, this document does not repeat all information included in the Worksheet comments. As such, this document should be consulted in conjunction with the Worksheet comments. The child option on the Worksheet should be used for evaluating lead exposure under residential land use scenarios unless exposure to children does not occur (such as a military barracks). Site-related data are entered in cells B8 and B9 of the worksheet. The default value for respirable dust (Cell B9) may be used when site-specific data are not available. Cells C13 through D26 contain exposure parameters which are generally not site specific. Departure from default values in cells C13 through D26 must be identified and justified. Numerical values in other cells are generally formulas, and although they may be changed for various purposes, any results obtained from the modified spreadsheet should not be represented as having come from the unmodified version of LeadSpread 9.

m) Worksheet Protection
The worksheet is protected except for the input cells (B8 and B9) to avoid inadvertent changes in formulas. If you wish to alter exposure parameters or formulas, you may use the unprotect feature of Excel to unprotect the sheet. There is no password (the password field should be left blank, and the ‘enter’ key clicked). If the results will be submitted to DTSC, you will be required to identify and justify any changes other than to the input cells. We recommend that any proposed alternate values for "Geometric Standard Deviation Blood Lead", "Baseline Blood Lead", or "Target Blood Lead level of concern” be discussed with the HERO toxicologist assigned to the site.

n) Default Parameters.
The default "Baseline Blood Lead" recommended by DTSC is 0 µg/dL. Since the target Blood Lead level of concern is a source-specific, incremental change due to soil/dust exposures only (see discussion above), no baseline Blood Lead is assumed. Variable defaults used to calculate the "PRG90" are shown on the Worksheet and explained in

the cell comments. Cells C13 through C26 contain exposure parameters and assumptions for an industrial land use scenario which are generally not site-specific.

o) Preliminary Remediation Goals (PRGs) and Use of PRGs for Site Evaluation.

The LeadSpread 9 Worksheet PRG90 calculations are provided for residential and industrial land use scenarios. The PRG90s represent concentrations in exterior soil and interior dust that will result in a 90th percentile estimate of incrementally increased blood lead in a child or the fetus of a pregnant adult equal to 1 µg/dL. While DTSC has historically used the 99th percentile estimate of blood lead, HERO considers the 90th percentile of the distribution appropriate for use in evaluating lead exposures given that the target blood lead level of concern was updated to the health-protective criterion of 1 µg/dL, from 10 µg/dl. For most sites without special circumstances, such as markedly elevated or reduced lead soil bioavailability, the difference in predicted incremental blood lead and IQ change for exposures to soil lead between 70 mg/kg and 77 mg/kg is within the LeadSpread model uncertainty and does not exceed the *de minimis* level of 1 IQ point identified by OEHHA. The current residential lead (Pb) soil screening level is 80 mg/kg, based on an estimated increase in blood Pb in a 90th percentile child of 1 µg/dL. At 80 mg/kg soil lead concentration, LeadSpread 9 estimates the increase in blood Pb in a 90th percentile child as 1.14 µg/dL which, in turn, is associated with an upper-bound estimate of a loss of 1 IQ point. The change is not discernable at one significant figure, the maximum justifiable significant figure. Results of IQ tests are reported as an integer. Fractional IQ points are not measured. The blood lead value of 1.14 would have to rise to 1.5 µg/dL (which would round up to 2.0) to be considered a significant increase. Therefore, HERO recommends that the remediation/mitigation level for residential soil exposure remain at the current residential default value of 80 mg/kg. Future development of better-defined childhood exposure parameters may change this recommendation. HERO implements this risk-based soil concentration as an Exposure Point Concentration (EPC), calculated as the 95 percent upper confidence limit on the arithmetic mean (95% UCL) of 80 mg/kg or less soil lead for the residential scenario and an industrial/commercial use 95% UCL of 500 mg/kg or less soil lead.

Regarding assessment of lead risk and evaluating cleanup options, if sufficient data are available, HERO recommends calculating the 95% UCL on the arithmetic mean lead concentration for each exposure area. If individual samples exceed the PRG90, it will not mean that the exposure area itself is in exceedance of the PRG90 as long as the 95% UCL itself is below 80 mg/kg for residential and 500 mg/kg for industrial/commercial, assuming “hot spots” are not present. If “hot spots” (i.e., geographically collocated areas of elevated concentration, or “outliers”, individual samples with elevated concentrations) are present, they must be addressed separately. For initial site screening where data are insufficient to calculate a 95% UCL, comparison of the maximum detected concentration to the PRG90 would be appropriate. If individual sample results exceed the PRG90, **depending on site-specific conditions and sampling results, additional investigation, evaluation, and potentially remediation may be warranted to address concerns about lead exposure.**

3) References

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