CALIFORNIA HUMAN HEALTH SCREENING LEVELS FOR BERYLLIUM

Review Draft
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Integrated Risk Assessment Branch
Office of Environmental Health Hazard Assessment
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Preface

In 2005, the California Office of Environmental Health Hazard Assessment (OEHHA) released a final document on the development of a list of soil screening numbers based on "protection of public health and safety" as required by Health and Safety Code Section 57008 (OEHHA, 2005). The screening numbers have no regulatory authority and are published solely as reference values that may be used by citizen groups, community organizations, property owners, developers, and local government officials to determine sites that would likely need no further action if a full risk assessment were conducted. How these soil screening levels should be applied is explained in "Use of California Human Health Screening Levels (CHHSLs) in Evaluation of Contaminated Properties," (Cal/EPA, 2005).

Beryllium CHHSLs

For a CHHSL to be calculated, a chemical must have a toxicity criterion A toxicity criterion mathematically relates a measure of exposure to a chemical to its toxic effect. For non-carcinogens it is generally the highest dose of the chemical not expected to cause a toxic effect. For a carcinogen it is the relationship between the risk of getting cancer caused by the chemical and the daily exposure to the chemical. In the OEHHA (2005) document, separate CHHSLs were developed for beryllium oxide, beryllium sulfate and all other forms of beryllium called "beryllium and compounds" because the three forms had different toxicity criteria. In 2005 the OEHHA Toxicity Criteria Database showed that all three were carcinogenic when inhaled. However, beryllium oxide and sulfate were considered carcinogenic when ingested, while "beryllium and compounds" was not. Residents and workers ingest far more soil at a site than the tiny amount that is inhaled after the soil is disturbed and becomes airborne dust. Therefore, the oral exposure generally drives the risk. This is why the CHHSLs for beryllium oxide and sulfate (considered carcinogenic when ingested) are so low compared to the CHHSL for beryllium and compounds (not considered carcinogenic when ingested)..

Beryllium Toxicity Criteria

The Toxicity Criteria Database is a Web site (www.oehha.ca.gov/risk/ChemicalDB/index.asp) that compiles the decisions of OEHHA's ongoing evaluation of chemical toxicity. (The Integrated Risk Information System (IRIS) is the equivalent for the United States Environmental Protection Agency (USEPA) Web site). Toxicity criteria are based on a scientific study in which animals or humans have been exposed to several dose levels of the chemical and the incidence of adverse health effects has been measured. These scientific studies must meet certain criteria to be used.

Federal and California legislation in the mid 1980s required rapid criteria development of chemical toxicity at both levels of government. Some of these criteria were rescinded on reevaluation. The Beryllium Health Assessment document published in 1987 (USEPA, 1987) was the basis for oral cancer criteria for some forms of beryllium for both USEPA and

California. Shortly after the publication of the Beryllium Health Assessment document, both USEPA and OEHHA listed both oral and inhalation toxicity criteria for various forms of beryllium. USEPA reevaluated the 1987 Health Assessment document and scientific basis for calling beryllium oxide and beryllium sulfate carcinogenic by the oral route. The USEPA withdrew its oral potency factor on the April 3, 1998.

The USEPA toxicity criteria database (IRIS) has the following statement for beryllium and beryllium compounds, "The basis for not using the Schroeder and Mitchener rat study (1975a) is that the incidences of gross or malignant tumors in the control and beryllium-exposed groups were not significantly different." The Schroeder and Mitchener rat study (1975) was the previous basis for considering beryllium carcinogenic by the oral route. USEPA also stated, "The oral database is considered inadequate for the assessment of carcinogenicity." (IRIS, 1998). As a result, the IRIS Web site only lists a non-cancer Reference Dose (RfD) for oral exposure to beryllium.

Following the USEPA reevaluation, OEHHA reviewed the oral carcinogenicity for beryllium to determine a drinking water health goal (Public Health Goal; PHG). In the PHG document (OEHHA, 2003), OEHHA concurred with the USEPA decision and based the drinking water health goal for all beryllium compounds on a non-cancer effect. OEHHA states, "In this case the chemical is a known human carcinogen, based on exposures by the inhalation route, but oral cancer potency cannot be determined." (OEHHA, 2003).

The OEHHA PHG for beryllium is based on the same non-cancer scientific study used to determine the USEPA RfD , however, it is 10 times lower. This is because, after OEHHA identifies an appropriate study upon which to base the PHG, a No Observable Effect Level (NOAEL) is determined. OEHHA and USEPA identified the same NOAEL. The second step is to divide the NOAEL by an Uncertainty Factor (UF) that accounts for the uncertainty in extrapolating the NOAEL in animals to one for humans which was the same for OEHHA and USEPA. When OEHHA suspects that a chemical could cause cancer but lacks a credible study on which to base a cancer potency, the UF is increased 10-fold on the non-cancer criterion which was the case for beryllium. Therefore, the beryllium PHG is based on a toxicity criterion of 0.0002 mg/kg-d. The USEPA RfD, on which the 2005 beryllium and beryllium compounds is based, is 0.002 mg/kg-d.

Calculation of New Beryllium CHHSLs

Calculations are shown below for new CHHSL values for beryllium oxide, beryllium sulfate and "beryllium and compounds" and they will replace the values from the 2005 document. This is done in order to make the CHHSLs consistent with the most recent OEHHA toxicity evaluation. Two changes are required for consistency. First, the less health protective USEPA toxicity criterion of 0.002 mg/kg-d used to compute the 2005 beryllium and beryllium compounds CHHSL will be replaced with the toxicity criterion used to compute the OEHHA PHG. Second, none of the toxicity criteria used will be based on an oral cancer potency value.

Cancer Calculations

The OEHHA inhalation cancer slope factor for beryllium sulfate is 3000 $(mg/kg\text{-}d)^{-1}$. For all other beryllium compounds including beryllium oxide, the inhalation slope factor is 8.4 $(mg/kg\text{-}d)^{-1}$. The equations used to compute a CHHSL when an inhalation slope, but not an oral slope factor, is available is:

Residential CHHSL based on inhalation of cancer-causing dust

$$CHHSL_{res} = \frac{TR \times AT \times PEF}{CSF_i \times EF_r \times \left(\left(\frac{IR_a \times (ED_r - ED_c)}{BW_a} \right) + \left(\frac{IR_c \times ED_c}{BW_c} \right) \right)}$$

Where:

TR is the target risk - 10^{-6} (one in a million)
AT is 70 year lifetime in days called an averaging time 25550 days
PEF is the particulate emission factor - 1.316 x 10^9 m^3 air/kg soil
CSFi is the cancer slope factor for inhalation - 3000 $(mg/kg\text{-}d)^{-1}$ beryllium sulfate and 8.4 $(mg/kg\text{-}d)^{-1}$ for all other forms of beryllium including beryllium oxide.
IRa is the inhalation rate of an adult - 20 m^3/d
IRc is the inhalation rate of a child - 10 m^3/d
EFr is the exposure frequency for a resident - 350 days per year
EDr is the total exposure duration of a resident - 30 years
EDc is the exposure duration of a resident as a child - 6 years
BWa is the body weight of an adult – 70 kg
BWc is the body weight of an adult – 15 kg

Solving this residential equation modeling inhaled dust with these parameters for beryllium sulfate gives a CHHSL of 2.9 mg/kg. For all other forms of beryllium including beryllium oxide the CHHSL based on inhaled dust is 1043 mg/kg. CHSSLs are rounded to two significant figures yielding 2.9 and 1000 mg/kg, respectively.

Commercial/Industrial CHHSL based on inhalation of cancer-causing dust

$$CHHSL_{ind} = \frac{TR \times AT \times PEF}{\frac{CSF_i \times IR_w \times EF_w \times ED_w}{BW_w}}$$

Where:

TR is the target risk - 10^{-6} (one in a million)
AT is 70 year lifetime in days called an averaging time - 25550 days
PEF is the particulate emission factor - 1.316 x 10^9 m^3 air/kg soil

CSFi is the cancer slope factor for inhalation - 3000 $(mg/kg\text{-}d)^{-1}$ beryllium sulfate and
8.4 $(mg/kg\text{-}d)^{-1}$ for all other forms of beryllium including beryllium oxide.
IRw is the inhalation rate of an worker - 20 m^3/d
EFw is the exposure frequency for a worker - 250 days per year
EDw is the total exposure duration of a worker - 25 years
BWw is the body weight of a worker - 70 kg

Solving this industrial equation modeling inhaled dust with these parameters for beryllium sulfate gives a CHHSL of 6.3 mg/kg. For all other forms of beryllium including beryllium oxide the CHHSL based on inhaled dust is 2242 mg/kg. CHSSLs are rounded to two significant figures yielding 6.3 and 2200 mg/kg, respectively.

Non Cancer Calculations

The OEHHA PHG drinking water criterion is based on a RfD that is 10-fold less than the one published by the USEPA. This value is 0.002 mg/kg-d. This value is used in the calculations below.

Residential CHHSL based on noncancer health effects to a child

$$CHHSL_{res} = \frac{THQ \times BW_c \times 365}{EF_r \times \left(\left(\frac{IRS_c}{RfD_{oral} \times 10^6} \right) + \left(\frac{AF_c \times SA_c \times ABS}{RfD_{oral} \times 10^6} \right) + \left(\frac{IRA_c}{RfD_{inh} \times PEF} \right) \right)}$$

Where:

THQ is the target hazard quotient – 1.0
PEF is the particulate emission factor - 1.316×10^9 m^3 air/kg soil
RfDoral is the OEHHA reference dose for oral exposure - 0.0002 mg/kg-d
RfDinh is the USEPA reference dose for inhalation exposure - 0.00000571 mg/kg-d
IRc is the inhalation rate of a child - 10 m^3/d
IRSc is the soil ingestion rate of a child 200 mg/d
EFr is the exposure frequency for a resident - 350 days per year
EDc is the exposure duration of a resident as a child - 6 years
BWc is the body weight of a child - 15 kg
AFc is the soil to skin adherence factor for a child- 0.2 mg/cm^2
SAc is the surface area of skin to which soil can stick for a child – 2800 cm^2/d
ABS is the percent of chemical that can be absorbed through the skin -1%

Solving this residential equation modeling ingestion, inhalation and dermal contact with these parameters gives a CHHSL of 16 mg/kg.

Commercial/Industrial CHHSL based on noncancer health effects to a worker

$$CHHSL_{ind} = \frac{THQ \times BW_w \times 365}{EF_w \times \left(\left(\frac{IRS_w}{RfD_{oral} \times 10^6} \right) + \left(\frac{AF_w \times SA_w \times ABS}{RfD_{oral} \times 10^6} \right) + \left(\frac{IRA_w}{RfD_{inh} \times PEF} \right) \right)}$$

Where:

THQ is the target hazard quotient - 1.0
PEF is the particulate emission factor - 1.316 x 10^9 m^3 air/kg soil
RfDoral is the OEHHA reference dose for oral exposure - 0.0002 mg/kg-d
RfDinh is the USEPA reference dose for inhalation exposure - 0.00000571 mg/kg-d
IRw is the inhalation rate of a worker - 20 m^3/d
IRSw is the soil ingestion rate of a worker 100 mg/d
EFw is the exposure frequency for a worker - 250 days per year
EDw is the exposure duration of a resident as a worker - 25 years
BWw is the body weight of an adult - 70 kg
AFw is the soil to skin adherence factor for a worker- 0.2 mg/cm^2
SAw is the surface area of skin to which soil can stick for a worker - 3300 cm^2/d
ABS is the percent of chemical that can be absorbed through the skin -1%

Solving this industrial equation modeling ingestion, inhalation and dermal contact with these parameters gives a CHHSL of 190 mg/kg.

Conclusion

Summary of 2005 CHHSLs for Beryllium (mg/kg soil)

Scenario	Residential		Commercial/Industrial	
Effect	Cancer	Non-cancer	Cancer	Non-cancer
Beryllium and Compounds	--	150	--	1700
Beryllium Oxide	0.091	--	0.41	--
Beryllium Sulfate	0.00021	--	0.00095	--

Summary of Recalculated CHHSLs for Beryllium (mg/kg soil)

Scenario	Residential		Commercial/Industrial	
Effect	Cancer	Non-cancer	Cancer	Non-cancer
Beryllium and Compounds	--	16	--	190
Beryllium Oxide	1000	--	2200	--
Beryllium Sulfate	2.9	--	6.3	--

Because the inadvertent ingestion of soil drives these calculations, eliminating the oral cancer potencies for beryllium oxide and beryllium sulfate dramatically increases the CHHSLs from those published previously. Likewise, decreasing the oral RfD by a factor of 10 reduced the new CHHSL for beryllium and beryllium compounds 10-fold.

Summary of Updated 2008 CHHSLs for Beryllium (mg/kg soil)

Scenario	Residential	Commercial/ Industrial
Beryllium Sulfate	2.9	6.3
All Other Beryllium Compounds	16	190

The residential CHHSL for beryllium sulfate is 2.9 mg/kg and the industrial CHHSL is 6.3 mg/kg. For all other forms of beryllium (including beryllium oxide), the non-cancer residential value of 16 is lower than the cancer residential value of 1000. Therefore, the residential CHHSL is 16 mg/kg. For all other forms of beryllium (including beryllium oxide), the non-cancer commercial/industrial value of 190 is lower than the cancer commercial/industrial value of 2200 mg/kg. Therefore, the commercial/industrial CHHSL is 190 mg/kg.

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