

US EPA ARCHIVE DOCUMENT

Issue: Short- and Intermediate-term Endpoint Selection for Inorganic Arsenic

For inorganic arsenic, the data of Franzblau et al (1989) and Mizuta et al (1956) using a LOAEL value of 0.05 mg/kg/day is proposed for selection of short-term and intermediate-term incidental oral endpoints as well as short-term and intermediate-term dermal endpoints. An acceptable Margin of Exposure value of 100 is also proposed. The acceptable Margin of Exposure value includes a 10x factor for intraspecies variation as well as a 10x factor for use of a LOAEL value and the severity of the effects observed in the Mizuta study.

Question 1: Please comment on the Agency's selection of the 0.05 mg/kg/day LOAEL value for use in assessing risks to the general population as well as children from short-term and intermediate-term incidental oral and dermal exposures, and the appropriateness of the use of a 10x factor for severity of the toxic effects observed in the Mizuta study. Please provide an explanation and scientific justification for your conclusions as to whether the presented data are adequate or whether other data should be considered for selection of this endpoint.

Issue: Relative Bioavailability of Inorganic Arsenic

The bioavailability of inorganic arsenic is dependent on the matrix in which it exists. For purposes of this discussion, the relative bioavailability of inorganic arsenic after ingestion of arsenic-contaminated soil is defined as the percentage of arsenic absorbed into the body from soil compared to that of arsenic administered in drinking water. Arsenic in drinking water is in a water-soluble form, and bioavailability by this route is high (i.e. 95-100%). Arsenic in soil, however, has reduced bioavailability due to existence in a water-insoluble form or its interaction with other soil constituents that impair absorption.

The available data on urinary and fecal recovery of arsenic after an intravenous dose of sodium arsenate in experimental animals compared to recovery after administration of sodium arsenate to experimental animals in soil was examined. Based on these data, a value of 25% bioavailability was selected for arsenic from soil ingestion. This value is based upon the data of Roberts et al. (2001) and Freeman et al. (1995) using non-human primates. These data were felt to best represent relative bioavailability of inorganic arsenic in soil based on the use of non-human primates and the physiological similarity in the pattern of metabolism with humans, and the use of CCA-contaminated soil in the study for estimation of bioavailability.

Question 2: Please comment on the choice of this data set and value chosen for representation of the relative bioavailability of inorganic arsenic from ingestion of arsenic-contaminated soil. Please discuss the strengths and weaknesses of the selected data and also provide an explanation as to whether this 25% value is appropriate for estimation of bioavailability in children.

Issue: Dermal Absorption Value for Inorganic Arsenic

A value of 6.4% for the dermal absorption of arsenic was selected to represent absorption from dermal contact with inorganic arsenic. This value is based upon the data of Wester et al. (1993) and represents percent absorbed dose of arsenic applied to the skin in a water solution. Although this value is slightly higher than the value of 4.5% obtained for arsenic applied in soil, the mean values for absorption from water and soil both showed significant variability (i.e. $6.4\% \pm 3.9\%$ in water, $4.5\% \pm 3.2\%$ in soil) such that use of the 6.4% dermal absorption value was selected. It is observed in this study that a higher dose on the skin resulted in lower dermal absorption as noted above, but the data in this study suggests sufficient variability in the absorption such that use of the 6.4% dermal absorption value is sufficiently but not overly conservative.

Question 3: Please comment on the selection of the value of 6.4% for dermal absorption of inorganic arsenic and whether or not this value will be appropriate for use in all scenarios involving dermal exposure to arsenic from CCA-treated wood, including children's dermal contact with wood surface residues and contaminated soils.

Issue: Selection of Hazard Database for Hazard Characterization of Inorganic Chromium in CCA-Treated Wood

Hazard data show clearly that Cr (VI) demonstrates more significant toxicity than Cr (III). However, there is little data delineating the valence state of chromium in compounds that leach from in-service CCA-treated wood (Lebow, 1996). Interconversion of Cr (VI) and Cr (III) in the environment is observed (Cohen et al., 1999), and at least one study has reported measurable levels of hexavalent chromium in soils (Lebow, 1996). In-service CCA-treated wood contains mainly chromium (III), due to reduction of chromium (VI) during fixation. However, when fixation conditions are not ideal or when storage temperatures are low, Cr (VI) is observed to be present in leachate from the treated wood and in addition, conditions in some soil types can result in conversion of leached Cr (III) to Cr (VI).

Question 4: As available monitoring data do not differentiate among chromium species found in CCA dislodgeable residues on wood surfaces and in soils, and as Cr (VI) is the more toxic species of chromium, please comment on whether use of the hazard data for chromium (VI) is the best choice for characterizing hazard and risk from exposure to chromium as a component of CCA-treated wood. Please provide a scientific explanation and justification for your recommendation on the choice of either the chromium (III) or chromium (VI) hazard database.

Issue: Short- and Intermediate-term Endpoint Selection for Inorganic Chromium

For inorganic chromium (VI), OPP proposes using the developmental toxicity study of Tyl (MRID 42171201) with a NOAEL value of 0.5 mg/kg/day [0.12 mg/kg/day chromium equivalents] and an MOE of 100 (10x for interspecies variation, 10x for intraspecies variation) for selection of short-term and intermediate-term incidental oral endpoints.

Question 5: Please comment on the Agency's selection of the 0.5 mg/kg/day NOAEL value for use in assessing risks to the general population as well as children from short-term and intermediate-term incidental oral exposures to inorganic chromium as contained in CCA-treated wood. Please provide an explanation and scientific justification for your conclusions as to whether the presented data are adequate or whether other data should be considered for selection of these endpoints.

Issue: Selection of Endpoints for Dermal Risk Assessments for Inorganic Chromium

Dermal exposure to chromium has been demonstrated to produce irritant and allergic contact dermatitis, and chromium is also one of the most common contact sensitizers in males in industrialized countries (IRIS, 2000). The relative potency of Cr (VI) and Cr (III) in causing dermal effects has been estimated to differ by approximately 50-fold (Bagdon, 1991) but both produce irritation and dermal sensitization. In the OPP HIARC review of selection of dermal toxicity endpoints, it was concluded that skin irritation and skin allergenicity are the primary effects of concern from dermal exposure to Cr(VI), as these effects are the predominant response from dermal exposure to inorganic chromium. Thus, endpoints based on systemic effects from dermal exposure were not selected.

Question 6: Please comment on whether the significant non-systemic dermal effects from dermal exposure to inorganic chromium should form the basis of dermal residential risk assessments, and, if so, how the Agency should establish a dermal endpoint for such an assessment.

Issue: Selection of Parameters and Methodology for Characterizing Child Exposures

OPP intends to develop realistic exposure scenarios and dose estimates for characterizing potential dermal/oral ingestion exposures to children in playground settings from contact with dislodgeable As and Cr residues on CCA-treated wood playground structures and in CCA-contaminated soils. In keeping with EPA policy, OPP would like its estimates to characterize both the middle and upper end of the range of potential exposure values. (The "high end" of exposure is defined as a level of exposure which is likely to be higher than experienced by at least 90% of the population, but not higher than the level experienced by the maximally exposed individual.) Following EPA guidance on conducting exposure assessments, OPP intends to rely on "mean value" (central tendency) data for calculating the lifetime average daily doses (LADDs) used for the cancer

assessment, and “maximum value” (high end) data for calculating the average daily doses (ADDs) used for the non-cancer assessment.

OPP expects to use a combination of central tendency and high end values for the different parameters of the exposure equations, as identified below.

Exposure Parameters Proposed for Use in Conducting the Child Exposure Assessment

<u>General Variables:</u>	Age	3 yr old	central tendency
	Body Weight	15 kg	central tendency
	<u>Surface Area:</u> hands, arms, legs	1640 cm ²	high end
	3 fingers	20 cm ²	central tendency
	<u>Playground activity:</u> hours / day	1 hr	central tendency
	days / year	130 days	central tendency
	years / lifetime	6 yrs out of a 75 yr lifetime	central tendency
<u>Scenario Specific Variables:</u>	Soil Adherence Factor	1.45 mg/cm ²	central tendency
• Dermal Contact with Soil			
• Oral Ingestion of Residues from Hand-to-Mouth Contact with Wood	Exposure time (hrs/day spent for hand-to-mouth activity)	1 hr/day and 3 hrs/day	central tendency and high end
	Hand-to-Mouth Frequency (events/hour)	9.5 events/hr and 20 events/hr	central tendency and high end
	Fraction Ingestion	50% removal efficiency	central tendency
• Oral Ingestion of Soil Residues	Soil Ingestion Rate	100 mg/day and 400 mg/day	central tendency and high end

Question 7. Please comment on whether OPP’s choices of central tendency and high end values for different parameters should, collectively, produce estimates of the middle and high end of the range of potential exposures. If the Panel thinks that OPP’s approach may not estimate the high ends of the exposure range (because it produces values that are either higher or lower than the upper end of the exposure range), please comment on what specific values should be modified to produce estimates of the high end of potential exposure.

EPA recognizes that there are many parameters that affect the level of potential exposure and that each of these parameters may vary. Probabilistic (e.g., Monte Carlo) techniques

are capable of using multiple data sets which reflect the variability of parameters to produce estimates of the distribution of potential exposures. OPP has identified a number of data sets that contain information on the variability of parameters affecting the levels of exposure to CCA residues experienced by children as a result of their playground activities. Nonetheless, OPP intends to develop deterministic estimates of potential exposure using selected values (either central tendency or high end) for different parameters, in such a manner that the estimates describe both the middle and high end of the range of exposures.

Question 8: Please comment on whether the existing data bases on the variability of the different parameters affecting potential exposure are adequate to support the development of probabilistic estimates of potential exposure. If the Panel regards the data bases as adequate for that purpose, please identify which parameters should be addressed using a distribution of values and which data bases should be used to supply the distribution for particular parameters.

Issue: Transfer of Residues from Wood Surface to Skin

In lieu of appropriate data on residue transfer from wood to skin surfaces, OPP proposes to rely on assumptions for residue transfer from turf as a surrogate. A one-to-one relationship is assumed between the transferable residues on turf and the surface area of the skin after contact (i.e., if the transferable residue on the turf is 1 mg/cm², then the residue on the human skin is also 1 mg/cm² after contact with the turf). This is based on OPP's Residential SOP's (April, 2000). OPP plans to apply this one-to-one relationship to the current assessment, assuming a one-to-one relationship between the dislodgeable residues on the wood surface and the surface of the skin after contact.

Question 9: OPP is assuming that a one-to-one relationship applies to the transfer of residues from wood to skin. The Panel is asked to address whether this is a reasonable assumption, and if not, to provide guidance on other approaches.

Issue: Selection of a Soil Adherence Factor

The Soil Adherence Factor (AF) is defined as the amount of soil which adheres to the skin. The AF is highly dependent on the soil type, moisture content of soil and skin, amount of time the soil contacts the skin, and human activities. OPP adopted a dermal exposure scenario for children touching CCA-contaminated soil which relies on an AF of 1.45 mg/cm² (U.S.EPA's Superfund RAG, 1989) for hand contacting commercial potting soil in lieu of playground soil. A recently drafted report (U.S.EPA's Superfund RAG, Part E., Supplemental Guidance for Dermal Risk Assessment, draft, 2000), recommended an activity-specific surface area weighted AF value for a child resident at a day care center (1 to 6 years old) of 0.2 mg/cm².

Question 10: The Panel is asked to comment on whether the proposed AF of 1.45 mg/cm² for hand contact with commercial potting soil is a realistic value for use in estimating the transfer of residues from playground soil to skin in this assessment.

Issue: Variability of Residue Data Available for Soil and Wood.

The soil and wood residue data being considered for this assessment has been generated over the last 25 years. There are several variables influencing the consistency of the data:

- Data were gathered and analyzed by several different research laboratories
- Data were collected at different geographic sites
- Differences in wood types and treatments between data sets

Additionally, the leaching rates of arsenic and chromium (to both the wood surface and the soil) are highly dependent on factors such as wood type, degree of weathering, age of wood, moisture content, pressure treatment process and retention time, use of coatings/sealants, and variations in the analytical and sampling techniques between laboratories.

OPP summarized the residue data by selecting and recommending some of the mean and maximum values from each study in order to compare the degree of leaching from the wood and the level of contamination in the soils. The “mean” data will be used to develop the lifetime average daily doses (LADDs) for the cancer assessment, and “maximum” data used in developing the average daily doses (ADDs) for the non-cancer assessment.

Question 11: OPP will need to calculate intermediate-term, and possibly long-term exposures in this assessment using available wood/soil residue data. The Panel is asked to recommend a credible approach for selecting residue data values for use in OPP’s risk assessment, taking into consideration the inherent variability of the data sets. Please advise us on which values are best for representing central tendency and high end exposures. Also, the Panel is asked to discuss the feasibility of combining data from individual data sets.

Issue: Combining Multiple Exposure Scenarios into a Comprehensive Estimate of Risk

Children playing on playgrounds containing CCA-treated wood structures will be exposed to arsenic and chromium residues on wood surfaces and in soils via oral and dermal routes. OPP has discussed four proposed exposure scenarios individually in the exposure assessment; however, to adequately assess the risks to children from exposure to arsenic and chromium residues through playground contact with wood and soil media, all four scenarios must be considered concurrently.

Question 12: Does the Panel have any recommendations for combining the four scenarios (oral/wood, dermal/wood, oral/soil, dermal/soil) such that a realistic

aggregate of these exposure routes may be estimated?

Issue: Inhalation Exposure Potential from Wood/Soil Media

The Agency has selected a NOAEL value of $2.4 \times 10^{-4} \text{ mg/m}^3$ taken from the 1998 IRIS update for Cr(VI) using the study of Lindberg and Hedenstierna (Arch Environ Health 38(6):367-374) who observed ulcerations, perforations of the nasal septum and pulmonary function changes in 104 workers (85 males, 19 females) exposed in chrome plating plants at a concentration of $7.14 \times 10^{-4} \text{ mg/m}^3$. The NOAEL value selected is intended to represent an endpoint for use in inhalation risk assessments representative of any duration of exposure.

OPP does not propose to evaluate potential exposures via the inhalation route for the child playground exposure assessment. The Agency anticipates that the inhalation potential from contact with either CCA-treated wood or CCA-contaminated soil is negligible. Neither arsenic *As(V)* nor chromium *Cr(VI)* residues are volatile on the surfaces of treated wood, nor readily available as respirable airborne particulate concentrations. During play activities in CCA-contaminated soil, any airborne soil-bound residues that a child might inhale through the nose or mouth are not anticipated to contribute significantly to the overall exposure (i.e., exposure will be insignificant compared to the oral dose attributed to soil ingestion or hand-to-mouth activities).

Question 13: Can the Panel comment on whether OPP should conduct a child playground inhalation exposure assessment, taking into consideration the hazard profile for chromium (VI) as an irritant to mucous membranes? If so, can the Panel comment on whether the endpoint described above is appropriate for assessing the risk to children from such an exposure?

Issue: Consideration of Buffering Materials as a Source of Exposure

The CPSC specifies suitable loose-fill surfacing materials (e.g., wood chips/mulch, sand, gravel, and shredded rubber tires) for use under and around public playground equipment as shock-absorbing buffers (i.e., “buffering materials”) to protect children from injury during a fall. (Handbook for Public Playground Safety, U.S. CPSC, Pub. No. 325). Concerns surrounding use of these buffers include the potential for CCA compounds to leach from the CCA-treated playground equipment and absorb into the buffering materials. In addition, these buffers may include wood mulch products originating from recycled construction and demolition (C&D) debris that may contain varying quantities of CCA-treated wood. Coupling CCA-treated playground equipment with playground barriers made from recycled wood mulch containing CCA-treated wood may increase background levels of arsenic and chromium, posing greater human exposure and health concerns.

Leaching studies conducted in Florida by Townsend et al. (2001) on new CCA-treated wood samples (wood blocks, chipped wood mulch, and sawdust) indicated that the concentrations of metals in leachate solutions were higher for wood processed into

chips/mulch or sawdust over wood blocks. The degree to which wood leaches appears to be dependent on particle size since wood chips/mulch have increased surface areas available for leaching, and consequently exposure, over dimensional lumber.

Currently there are limited data available which adequately address the effects of leaching of CCA-treated wood compounds from playground structures to buffering materials used under and around these structures. A recent report released by Florida's Alachua County Board of County Commissioners (2001) presents soil and mulch data from limited arsenic sampling conducted by Environmental Protection Department staff at five county owned parks. Tire chip and wood mulch buffering materials sampled at half-depth (2"-6") from areas immediately adjacent to CCA wood playground borders, playground posts, and within playground areas (between borders/posts) yielded arsenic concentrations for wood mulch of 43.1 - 61.2 mg/kg (border) and 0.5 mg/kg (play areas), and for tire chips 3.5 - 70.3 mg/kg (border), 10.3 - 80.3 mg/kg (posts) and 0.4 - 0.9 mg/kg (play areas). Each park had a liner in place between the mulch material and the bare soil.

Question 14: Data on the effectiveness of reducing exposure by using buffering materials are limited. Does the Panel have recommendations as to whether additional studies to obtain this information are warranted? Does the Panel have suggestions on how OPP can best evaluate child exposures attributed to contact with CCA-contaminated buffering materials ?

Issue: Effectiveness of Stains/Sealants/Coatings at Reducing Leaching of CCA Compounds from Treated Wood

Several researchers have reported that stains/sealants/coatings can reduce the rate of leaching of CCA compounds from treated wood and that the effectiveness of these coating materials over time varies greatly, depending on the type of surface coating used and environmental conditions effecting the wood. Stilwell (1998) reported over a 95% reduction in dislodgeable arsenic residues from CCA-treated wood surfaces coated with polyurethane, acrylic or spar varnish, and an average of 90% reduction for oil-based alkyl resins for samples tested one year after a sealant was applied. CDHS (1987) reported 96%, and 82% reductions in dislodgeable arsenic from stained CCA-treated wood surfaces after one month and 2 years, respectively. Lebow and Evans (1999) reported that staining CCA-treated wood surfaces reduced leaching of arsenic by 25%.

Question 15: The Panel is asked to comment as to whether stains, sealants and other coating materials should be recommended as a mitigation measure to reduce exposure to arsenic and chromium compounds from CCA treated wood. If so, can the Panel comment on the most appropriate way for the Agency to recommend effective coating materials when the current data on long-term performance are limited and sometimes inconsistent, and should the Agency specify a time interval for the re-application of these selected coating materials? Can the Panel make recommendations for additional studies?

