# Human Health Risk Assessment for Long-term Residential Use of Ironite® Lawn and Garden Nutrient Supplement

Prepared By

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*Prepared for*
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# EXECUTIVE SUMMARY

The objective of this risk assessment is to provide an evaluation of health risks that may result from exposure to soils that may become contaminated with metals present in Ironite® following long-term application on lawns and shrubs in a residential setting.

This report evaluates the potential for chronic systemic toxicity and carcinogenicity in child and adult residential receptors. The analysis considers exposures via ingestion, inhalation, and dermal contact. The report does not consider exposures that may occur as a result of the potential uptake of contaminants into terrestrial garden plants and trees.

The risk assessment is written using a deterministic methodology that is consistent with current risk assessment guidance issued by the United States Environmental Protection Agency (USEPA). Chemicals of concern (COCs) are selected using USEPA and Arizona Department of Health Services (ADHS) risk assessment guidance. Exposures are quantified assuming reasonable maximum exposure assumptions that incorporate USEPA standard default exposure factors. Exposure concentrations are modeled assuming that the product is used as suggested on the label for 30 years. Toxicity is assessed using current USEPA cancer slope factors and reference doses and CDC recommendations for the maximum percentage of children with blood lead levels in excess of 10 $\mu$g/dL. Incremental risks and noncancer hazards are quantitatively and qualitatively evaluated.

Arsenic, cadmium and lead were selected as the potential COCs in Ironite® . The concentrations of the COCs that may be present in surface soils following long term application of Ironite® were modeled using a conservative methodology that assumes that Ironite® is applied at the maximum recommended rates suggested on the label. Modeling was conducted using USEPA equations and assumptions. Area specific values were used where necessary. The potentially complete exposure route to the potential COCs in surface soil include ingestion, dermal contact, and inhalation of fugitive dust.

Soils beneath shrubs and trees where Ironite® has been applied would likely be exposed and available for human contact. However, the fraction of soil actually ingested from the areas where the product has been applied is likely to be much less than 100%. Nevertheless, for the purposes of this analysis, 100% of the soils ingested on a daily basis were assumed to be from the applied area. In addition, soils underneath lawns would likely be unavailable for direct contact since the physical presence of the grass would prevent soils from being exposed. Nevertheless, this risk assessment assumes that these soils represent a potentially complete exposure pathway.

The reasonable maximum excess lifetime cancer risk (ELCR) estimate from exposure to contaminants that may accumulate in soils underneath lawns following prolonged application of Ironite® in a residential setting is estimated to be 3E-5 (three-in-one-hundred-thousand). The reasonable maximum ELCR estimate from exposure to contaminants that may accumulate in soils underneath shrubbery following prolonged application of Ironite® in a residential setting is estimated to be 2E-5 (two-in-one-hundred-thousand). Both of these risk estimates are within the acceptable range of risk established by the USEPA.

The reasonable maximum Hazard Quotient (HQ) from exposure to contaminants that may accumulate in soils underneath lawns and shrubs following prolonged application of Ironite® in a residential setting is estimated to be less than 1 for both children and adults. The USEPA Integrated Environmental Uptake Biokinetic Model (IEUBK) model was used to evaluate the potential systemic hazard for lead since the USEPA has not established a reference dose for this metal. The results of the IEUBK analysis suggest that the accumulation of lead in soils from the use of Ironite® would not represent a health threat to children living in homes where it is applied. These results suggest that no systemic toxicity threat would be presented to either children or adults following prolonged use as directed of Ironite® on lawns and shrubs.

In summary, the cancer risk level for integrated residential exposure to metals that may accumulate in residential soils following long-term use of Ironite® as suggested on the label is within the acceptable range of risk according to the USEPA. The study also suggests that maximal residential childhood exposure to metals that may accumulate in residential soils following long-term use of Ironite® as suggested on the label would be below levels that would result in adverse noncancer health effects.

This report does not consider exposures that may occur as a result of the potential uptake of contaminants into terrestrial garden plants and trees. The analysis also does not consider the potential for adverse health effects as a result of direct contact with the product during application.

**Conclusion**

The accumulation of metals that may occur following prolonged use of Ironite® in a residential setting does not appear to represent a health risk to residents of homes where it is used if the product is applied in accordance with recommendations on the label.

# 1.0 INTRODUCTION

The objective of this risk assessment is to provide an evaluation of health risks that may result from exposure to soils that may become contaminated with metals present in Ironite® following long-term application in a residential setting.

## 1.1 Authority

This risk analysis is written under contract for the Arizona Department of Environmental Quality (ADEQ). This document was prepared using guidelines prescribed by the U.S. Environmental Protection Agency (USEPA) Risk Assessment Guidance for Superfund (RAGS), Volume I, Human Health Evaluation Manual: Part A (USEPA, 1989), RAGS Human Health Supplement (USEPA, 1991a,b), and the Arizona Department of Health Services (ADHS) Deterministic Risk Assessment Guidance (ADHS, 1997a).

## 1.2 Overview

The ADEQ is investigating whether the application of Ironite®, when used as suggested on the label, is protective of human health and the environment. As part of their investigation, the ADEQ asked the ADHS Environmental Health Sciences Section (EHSS) to evaluate the health risks to child and adult receptors from contact with soils that may become contaminated with metals in Ironite® following prolonged use of the product on shrubs/trees and lawns in a residential setting.

This report evaluates the potential for acute and chronic systemic toxicity and carcinogenicity in child and adult residential receptors. The analysis considers exposures via ingestion, inhalation, and dermal contact. The report will not consider exposures that may occur as a result of the potential uptake of contaminants into terrestrial garden plants and trees. The analysis also does not consider the potential for adverse health effects as a result of direct contact with the product during application.

The risk assessment is written using a deterministic methodology that is consistent with current risk assessment guidance issued by the USEPA. Chemicals of concern are selected using USEPA and ADHS risk assessment guidance. Exposures are quantified assuming reasonable maximum exposure assumptions that incorporate USEPA standard default exposure factors. Exposure concentrations are modeled assuming that the product is used as directed for 30 years. Toxicity will be assessed using current USEPA cancer slope factors and reference doses. Incremental risks and noncancer hazards are quantitatively and qualitatively evaluated.

### 1.3 Background Information

Ironite® is made by Ironite® Products Company of Scottsdale, Arizona. The key raw material utilized in the production of Ironite® is naturally occurring ore from the Iron King Mine, located in Humboldt, Arizona. Ore from the mine is crushed, ground, and put through a process in which other plant nutrients are added. The material is then bagged and sold as Ironite® . It has been used in the United States since 1956.

Ironite® is used as a nutritional soil supplement to provide zinc and other trace elements to plants growing in soil which are either deficient in these elements or in which plant uptake of iron content is inhibited. It is recommended by the manufacturer for use on lawns, vegetables, flowers, shrubbery, and trees. (RUST, 1998) Laboratory analyses Ironite® have shown that the concentrations of arsenic, lead, and cadmium in the product are in excess of Arizona Soil Remediation Levels (SRLs), suggesting that evaluating the product for its potential to accumulate in soils is warranted.

### 1.4 Goals and Objectives

The goal of this human health risk assessment will be to provide health risk information for use in risk management. The objective will be to provide an evaluation of human health risks that may result from exposure to soils that may become contaminated with metals present in Ironite® following long-term application in a residential setting.

## 2.0 CHEMICALS OF CONCERN

This section identifies the potential chemicals of concern (COCs) identified in Ironite® . Potential COCs were selected based upon their concentration in Ironite® product. Arsenic, cadmium and lead are the chemicals that meet the selection criteria for potential COCs.

### 2.1 Data Collection

ADHS staff purchased 10 containers of Ironite® in 5, 10 and 25 pound packages from 10 retail establishments in Maricopa County on July 7, 1998. The retail establishments and containers were selected at random. A 100-gram sample of product from each container was placed in a clean container and submitted to the ADHS inorganic environmental laboratory for analysis on July 8, 1998. Analyses for metals were conducted by the ADHS laboratory on July 15, 1998. A record of purchase locations, size and the analytical results are located in the Appendix.

### 2.2 Data Evaluation

The mean and the 95% upper confidence limit (UCL) of the mean concentrations of metals in the data set were calculated using the "Student's t distribution." The mean and 95% UCLs were calculated using reported concentrations or one-half the Sample Quantification Limit (SQL) for each sample.

The screening levels used for identifying potential COCs were Arizona Soil Remediation Levels (SRLs) (ADHS, 1997b). SRLs have been promulgated by ADEQ rule and are levels of contaminants in soil that do not represent a health risk under normal residential conditions.

### 2.3 Selection Methodology for Chemicals of Concern

Potential COCs were selected based upon their concentration in whole product granular Ironite® . The selection methodologies described below use soil screening criteria discussed in this section and current USEPA carcinogenicity Weight of Evidence (WoE) classifications.

The USEPA's Carcinogen Advisory Group has assigned WoE classifications to many chemicals. The WoE represents the carcinogenicity evidence from human and animal studies, and indicates the strength of the data. An A classification signifies that the chemical is a proven human carcinogen. Probable human carcinogens are designated as either B1, showing that studies in humans are strongly suggestive but not conclusive, or as B2 if the chemical has been conclusively carcinogenic in repeated animal studies but not conclusive in human studies. A chemical may be classified C, a possible human carcinogen, if a single high-quality animal study or several low-quality animal studies suggest carcinogenicity.  If there is insufficient human and animal evidence to determine the carcinogenicity of the chemical, it is classified as D.  A chemical conclusively shown to be non-carcinogenic to humans is in group E.  This designation is rare due to the difficulty in producing the necessary negative data.

Chemicals were eliminated as potential COCs in Ironite®  if there were no positive detections in the data set; or the highest detected value was less than the residential Arizona Soil Remediation Level (SRL) ***and*** the chemical is not recognized by the Integrated Risk Information System (USEPA, 1997) as a possible (WoE=C), probable (WoE=B1, B2), or known human (WoE=A) carcinogen.  All other chemicals for which analyses were conducted were retained as potential COCs.

### 2.4 Identification of Chemicals of Potential Concern

Arsenic, cadmium and lead have been selected as potential COCs in Ironite®.  Table 2.4 displays the maximum, minimum, mean, and 95% UCL concentrations of metals in Ironite®  in the samples analyzed. The table also displays the WoE and Arizona SRL for each of the constituents.  The final column indicates that arsenic, cadmium, and lead are the constituents that meet the selection criteria as potential COCs.

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**Table 2.4. Statistical Summary and Identification of Chemicals of Concern in Ironite®**

| Chemical Name | Max. (mg/kg) | Mean (mg/kg) | Std. Dev. | 95% UCL (mg/kg) | Freq. of Det. | Det. % | WoE | SRL Residential (mg/kg) | COC |
|---|---|---|---|---|---|---|---|---|---|
| Arsenic | 4900 | 4440 | 290 | 4648 | 10/10 | 100 | A | 10 | √ |
| Barium | 20 | 15.8 | 1.8 | 17 | 10/10 | 100 | D | 7700 | |
| Cadmium | 54 | 51.6 | 1.8 | 53 | 10/10 | 100 | B1/D | 38 | √ |
| Chromium | 18 | 13.7 | 2.1 | 15 | 10/10 | 100 | A/D | 2100 | |
| Cobalt | 14 | 12.3 | 0.9 | 13 | 10/10 | 100 | D | 4600 | |
| Copper | 370 | 310 | 41 | 339 | 10/10 | 100 | D | 2800 | |
| Iron | 110000 | 11000 | 0 | 11000 | 10/10 | 100 | D | NA | |
| Lead | 3100 | 2850 | 175 | 2975 | 10/10 | 100 | B2 | 400 | √ |
| Manganese | 700 | 645 | 25 | 663 | 10/10 | 100 | D | 3200 | |
| Nickel | 11 | 5.6 | 1.8 | 6.9 | 1/10 | 10 | A/D | 1500 | |
| Selenium | ND | ND | ND | ND | 0/10 | 0 | D | 380 | |
| Silver | 14 | 12.7 | 1 | 13.4 | 10/10 | 100 | D | 380 | |
| Zinc | 9000 | 8460 | 461 | 8789 | 10/10 | 100 | D | 23000 | |

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### 2.5 Data Quality

Standard Quality Assurance, Quality Control (QA/QC) procedures were followed in the analysis of the samples at the ADHS Laboratory for a multi-element metals screen for Ironite®. These procedures included calibration curves, controls, known reference material values, duplicates, spike and spike duplicates, method blanks, and method fortified blanks. The QA/QC data suggest that the results are generally consistent and are of adequate quality for use in this risk assessment.

# 3.0 EXPOSURE ASSESSMENT

This exposure assessment focuses on hypothetical human exposure to soils that may become contaminated with metals present in Ironite® following long-term application in a residential setting. The evaluation considers exposures that may occur as a result of direct contact with soils in residential lawns and shrubbery or gardens. The evaluation does not consider uptake and exposure via edible garden plants or exposures that may occur during application.

## 3.1 Exposure Pathways

This Section evaluates and identifies the potentially complete exposure pathways in the assessment.

### 3.1.1 Source and Receiving Media

The source of COCs in this analysis is assumed to be the use of Ironite® . Soil is assumed to be the receiving media.

### 3.1.2 Fate and Transport in Soil

COCs present in soil can be adsorbed in the soil matrix; percolate through soils or be released to the air through fugitive dust emissions. Adsorption can lead to immobility and increased resistance to chemical or biological degradation. Compounds that are soluble in water will be more mobile, increasing leaching and movement of the material.

Much of the mass of Ironite® consists of mine tailings that are high in iron. Mineralogic analysis of the COCs in Ironite® has been conducted by Davis and Drexler (RUST, 1998) indicate that the arsenic present in Ironite® is primarily composed (95%) of arsenopyrite (FeAsS), and that the mineral is encapsulated in refractory pyrite. The authors suggest that the pyrite coating "inhibits the solubilization of arsenic from the arsenopyrite."

Solubility studies conducted on Ironite® by Dr. Davis of Geomega (RUST, 1998), found that at a pH of 7, approximately 0.1 of As in the samples were solubilized in distilled water, suggesting that at least prior to weathering, the arsenic (As) in Ironite® would be sparingly soluble in Arizona soils.

Analyses of mine tailings from Mesa de Oro, California, conducted by the Science and Engineering Analysis Corporation in Sacramento, California (SEACOR, 1994) suggest that extractions conducted on the tailings found that approximately 25% of the As in the tailings were readily extracted by distilled water, suggesting that a significant amount of As in the samples was water soluble. These results suggest that at least a portion of the product may be water soluble.

In order to more accurately evaluate the mobility of Ironite®, the ADEQ asked Dr. Jack Watson of the University of Arizona Agricultural Extension Service to evaluate the mobility of Ironite® in typical Arizona soils under irrigation. The results of the analysis suggest that Ironite® is only slightly soluble under the conditions evaluated during their bench scale studies. These results suggest that Ironite® is marginally soluble in soils (University of Arizona, 1998). Therefore, this risk assessment will assume that the movement of metals in Ironite® in lawns and shrubbery is limited to the physical mixing of soil.

The physical mixing zone of soils in both lawns and soils beneath gardens and shrubs is assumed to be limited to 10 cm, or approximately 4 inches, which represents the depth of soil which is typically mixed during annual dethatching of bermuda grass. The physical mixing zone for shrubs and trees was also assumed to be 10cm, representing the depth of soil that is assumed to be mixed when working the Ironite® into the soil as suggested on the label.

### 3.1.3 Exposure Points and Routes

Potentially complete exposure pathways for this analysis include direct and indirect contact with soils that may become contaminated over time. Soils beneath shrubs and trees where Ironite® has been applied would likely be exposed and available for human contact. Soils underneath lawns would likely be unavailable for direct contact since the physical presence of the grass would prevent soils from being exposed. Nevertheless, this risk assessment assumes that these soils represent a potentially complete exposure pathway.

The potentially complete exposure routes include ingestion, dermal contact, and inhalation of fugitive dust. This analysis does not consider the potential for uptake into edible plants or exposures that may occur during application.

### 3.1.4 Summary of Complete Exposure Pathways

The following tables summarize current and potential future pathways at the site.

## Table 3.1.4.1: Current Exposure Pathway Summary for Ironite®

| Potential Exposed Population | Exposure Point | Exposure Route | Path Evaluated | Path Selected | Exposure Type | Rationale |
|---|---|---|---|---|---|---|
| **Soil** | | | | | | |
| Residents | Contaminated surface soils beneath lawns | Ingestion<br>Inhalation<br>Dermal | Yes<br>Yes<br>Yes | Yes<br>Yes<br>Yes | Unlikely<br>Unlikely<br>Unlikely | Contact with metal residuals unlikely due to the presence of a lawn, however ingestion, dermal contact and inhalation still considered possible |
| Residents | Contaminated surface soils beneath shrubs and trees | Ingestion<br>Inhalation<br>Dermal | Yes<br>Yes<br>Yes | Yes<br>Yes<br>Yes | Potential<br>Potential<br>Potential | Possible ingestion and dermal contact with surface soils, inhalation of fugitive dust, exposures possible from exposed soils |
| Residents | Uptake into terrestrial edible plants | Ingestion | No | No | Potential | Outside the scope of this risk assessment |
| Applicator | Exposures during application | Ingestion<br>Inhalation<br>Dermal | No<br>No<br>No | No<br>No<br>No | Potential<br>Potential<br>Potential | Outside the scope of this risk assessment |

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### 3.2 Quantification of Exposure Concentrations

Estimates of exposure concentrations and pathway specific intake doses must be made to quantify exposures. Repeated, prolonged (chronic) exposures are assumed. Exposures from ingestion, inhalation and dermal contact with soils will be quantified.

The potential for acute and chronic health effects from exposure to soils that may become contaminated with metals present in Ironite® following long-term application in a residential setting were evaluated assuming that Ironite® will be used on a lawn at the maximum recommended rate on the label of 1.5 lbs. per 100 $ft^2$ three times per year (2.19 kg/10 $m^2$ per year). Soils around shrubbery and trees were evaluated assuming the maximum recommended application rate of 1.5 lbs. per 100 $ft^2$ two times per year (1.46 kg/10 $m^2$ per year).

This assessment does not consider the naturally occurring concentrations of the COC that may be present in soils prior to using the product since the objective of this evaluation is to estimate the human health risk from the use of Ironite® .

Soil concentrations of the COCs were initially assumed to be 0 mg/kg. As Ironite® is added to the residential soil, the concentration of COC increases. Therefore, the concentration of metals would be expected to increase over the 30-year exposure interval, with lower concentration during the initial years, and increasing levels in the later years. Metal loading and concentrations were modeled using the application rates noted in this section. The 95% UCL concentration of each COC was assumed to be present in the product during each application. Table 2.4 displays the estimated concentration of each COC in the product. The formula for calculating the UCL is as follows:

$$UCL = \text{mean} + t_{(n-1)} * (\sigma/\sqrt{n})$$

Estimated COC concentrations at the end of each year of the 30-year exposure interval were calculated by quantifying the estimated metal loading in mg per 10 $m^2$ (using maximum label application rates) and dividing by the total mass of soil in the mixing zone. The model assumes a standard soil bulk density of 1700 $kg/m^3$. For lawns, the total mass of soil in the mixing zone was calculated by multiplying the 10 $m^2$ application/exposure area by 10 cm (4 inches), which represents the depth of soil which is typically mixed during annual dethatching of bermuda grass. For shrubs and trees, the total mass of soil in the mixing zone was calculated by multiplying the 10 $m^2$ application/exposure area by 10 cm (4 inches), which represents the depth of soil that is assumed to be used when working the Ironite® into the soil as directed. Losses of COCs due to leaching were calculated using the USEPA formula for calculating first order loss rates (USEPA, 1990a).

The value for the loss constant due to leaching (ksl) was derived from Equation 4-3 in the document entitled *Methodology for Assessing Health Risks Associated with Indirect Exposure to Conbustor Emissions* (USEPA, 1990a).

Values included in this equation for lawns include the average annual precipitation of 18.8 cm/yr and an average annual irrigation of 165 cm/yr, which represents the amount of water required to maintain a bermuda lawn in the summer and a rye grass lawn in the winter (Kent Newland, City of Phoenix, Phoenix Conservation Resource Division). A value for of 152 cm/yr was used for the evapotranspiration from a lawn (Dr. Paul Brown, University of Arizona College of Agriculture).

Values included in this equation for shrubs and trees include the average annual precipitation of 18.8 cm/yr and an average annual irrigation of 122 cm/yr, which represents a consumptive amount of water required to maintain a grapefruit tree (USDA, 1982). A value for of 106 cm/yr, which represents annual pan evaporation in Phoenix, was used for the evaporation at the tree site.

A soil volumetric water content of 0.15 mL/$cm^3$ was used with a soil depth from which leaching removal occurs of 10 cm. (ADHS, 1997b) The equation uses the chemical-specific soil water partitioning coefficient (Kd) for each constituent (USEPA, 1996a).

Equation 3.1 was used to estimate the concentration of each COC at the end of each application year (USEPA, 1990a).

$$\mathbf{Ct = (k_o/kM)(1\text{-}e^{-kt})} \qquad \text{Equation 3.1}$$

where:

| | | |
|---|---|---|
| Ct | = | concentration of the COC after time t (mg/kg) |
| $k_o$ | = | application rate of COC to soil (mg/year) |
| k | = | first order loss of COC from leaching (1/year) |
| M | = | mass of soil in 10 $m^2$ application area (kg) |
| e | = | natural log function |
| t | = | time (years) |

where:

$$\mathbf{k = \frac{P + I - EV}{\cdot\ Z \cdot\ (1.0 + (BD \cdot K_d/\ \ ))}}$$

and where

| | | | |
|---|---|---|---|
| k | = | loss constant due to leaching (L/kg) | Chemical-specific (L/kg) |
| P | = | average annual precipitation (cm/yr) | 18.8cm/yr |
| I | = | annual irrigation grass (cm/yr) | 165 cm/yr |
| $I_2$ | = | annual irrigation for shrubs (cm/yr) | 122 cm/yr |
| Ev | = | average annual evapotranspiration grass (cm/yr) | 152 cm/yr |
| $Ev_2$ | = | average annual pan evaporation grapefruit (cm/yr) | 106 cm/yr |
| | = | soil volumetric water content ($mL/cm^3$) | 0.15$mL/cm^3$ |
| Z | = | soil depth from which leaching removal occurs (cm) | 10 cm |
| BD | = | soil bulk density ($g/cm^3$) | 1.5 $g/cm^3$ |
| $K_d$ | = | soil water partitioning coefficient (mL/g) | Chemical-specific(mL/g) |

The mean concentration over the 30 year exposure period was used to quantify exposures for evaluating carcinogenicity. The predicted total concentration following 30 years of continuous exposure was used to estimate exposures for evaluating the potential for acute noncancer health effects.

Inhalation of nonvolatile chemicals adsorbed to respirable particles ($PM_{10}$) were assessed using a default Particulate Emission Factor (PEF) of 1. 316 x $10^9$ $m^3$/kg that converts a contaminant concentration in soil to a concentration of respirable particles in the air from fugitive dust emissions. The generic PEF was derived using USEPA default values which correspond to a receptor point concentration of approximately 0.76 µg/$m^3$. The relationship is derived by Cowherd (1985) for a rapid assessment procedure applicable to a typical hazardous waste site where surface contamination provides a continuous and constant potential for emission over an extended period.

The dispersion term (Q/C) has been derived from a modeling exercise using meteorological data from 29 locations across the United States (USEPA, 1996a). The dispersion model for particulates is the AREA-ST, an updated version of the USEPA Office of Air Quality Planning and Standards, Industrial Source Complex Model, ISC2. A default source size of 0.5 acre was chosen in calculating exposure concentrations. This is consistent with the default exposure area over which USEPA Region IX typically averages contaminant concentrations in soils.

### 3.4 Exposure Estimation Methods

*Arsenic and Cadmium*

The chronic daily intake (CDI) is the quantity of a chemical which is available for absorption at the exchange boundary. It is different from the absorbed dose, which represents the concentration of the chemical in blood. Equations 3.4.1 through 3.4.5 were used to quantify exposure and risk estimates for carcinogenic and systemic toxicity for each exposure pathway. Table 3.4.1 displays the exposure assumptions used under each scenario.

Adult and childhood exposures were integrated using EPA exposure assumptions to evaluate carcinogenicity. Childhood exposure assumptions were assumed to occur for the first six years, followed by 24 years of adult exposures. Equations 3.4.1 through 3.4.4 and Table 3.4 display the equations and exposure assumptions used to integrate childhood and adult exposures for carcinogenicity.

Age-adjusted integration was not used to evaluate exposures for the purposes of evaluating systemic toxicity. Exposure assumptions reflect childhood contact rates and body weight. The focus on children is protective of the higher daily intake rates by children and their lower body weight. Equation 3.5 and Table 3.4 display the equation and exposure assumptions for evaluating systemic toxicity.

*Lead*

Since the USEPA has not published an RfD or SF for lead, exposures have been developed using the USEPA Integrated Environmental Uptake Biokinetic Model (IEUBK) Model. The IEUBK model generates a probability distribution of blood lead levels for a population of children exposed to lead in a number of media. The distribution reflects the variability of blood lead levels in several communities. Lead exposures integrated in the model include dietary sources, drinking water, air, soil and household dust, and other sources.

The analysis used here uses program default exposures from dietary sources, drinking water, air and household dust, and other sources. Children were assumed to live in houses that do not contain lead-based paint. The concentration of lead in soil used in the analysis is the mean estimated concentration of lead in soils following 30 years of application of Ironite®.

**Equation 3.4.1: Integrated Ingestion Adjustment Factor for Residential Exposure to Carcinogens**

$$IFS_{adj} = \frac{ED_c \ x \ IRS_c}{BW_c} + \frac{(ED_r - ED_c) \ x \ IRS_a}{BW_a}$$

**Equation 3.4.2: Integrated Inhalation Adjustment Factor for Residential Exposure to Carcinogens**

$$InhF_{adj} = \frac{ED_c \ x \ IRA_c}{BW_c} + \frac{(ED_r - ED_c) \ x \ IRA_a}{BW_a}$$

**Equation 3.4.3: Integrated Dermal Adjustment Factor for Residential Exposure to Carcinogens**

$$SFS_{adj} = \frac{ED_c \ x \ AF \ x \ SA_c}{BW_c} + \frac{(ED_r - ED_c) \ x \ AF \ x \ SA_a}{BW_a}$$

**Equation 3.4.4: Combined Exposures to Carcinogenic Contaminants in Residential Soil**

$$ELCR = \frac{C_s \ x \ EF_r \ [(\frac{IFS_{adj} \ x \ CSF_o}{10^6 mg/kg}) + (\frac{SFS_{adj} \ x \ ABS \ x \ CSF_o}{10^6 mg/kg}) + (\frac{InhF_{adj} \ x \ CSF_i}{VF_s^{\ a}})]}{AT_c}$$

**Equation 3.4.5: Combined Exposures to Noncarcinogenic Contaminants in Residential Soil**

$$HQ = \frac{C_s \ x \ EF_r \ x \ ED_c \ [(\frac{1}{RfD_o} \ x \ \frac{IRS_c}{10^6 mg/kg}) + (\frac{1}{RfD_o} \ x \ \frac{SA_c \ x \ AF \ x \ ABS}{10^6 mg/kg}) + (\frac{1}{RfD_i} \ x \ \frac{IRA_c}{VF_s^{\ a}})]}{BW_c \ x \ AT_n}$$

## Table 3.4: STANDARD DEFAULT EXPOSURE FACTORS

| Symbol | Definition (units) | Default | Reference |
|---|---|---|---|
| CSFo | Cancer slope factor oral (mg/kg-d)-1 | -- | IRIS, HEAST |
| CSFi | Cancer slope factor inhaled (mg/kg-d)-1 | -- | IRIS, HEAST |
| RfDo | Reference dose oral (mg/kg-d) | | -- IRIS, HEAST |
| RfDi | Reference dose inhaled (mg/kg-d) | -- | IRIS, HEAST |
| BWa | Body weight, adult (kg) | 70 | RAGS (Part A), USEPA 1989 (EPA/540/1-89/002) |
| BWc | Body weight, child (kg) | 15 | Exposure Factors USEPA 1991 (OSWER No. 9285.6-03) |
| ATc | Averaging time - carcinogens (days) | 25550 | RAGS(Part A), USEPA 1989 (EPA/540/1-89/002) |
| ATn | Averaging time - noncarcinogens (days) | ED*365 | |
| SAa | 25% Surface area, adult (cm$^2$/day) | 5000 | Dermal Assessment, USEPA 1992(EPA/600/8-91/011B) |
| SAc | 25% Surface area, child (cm$^2$/day) | 2000 | Dermal Assessment, USEPA 1992 (EPA/ 600/8-9/011B) |
| AF | Adherence factor (mg/cm$^2$) | 0.2 | Dermal Assessment, USEPA 1992 (EPA/600/8-9/011B) |
| ABS | Skin absorption (unitless): | | |
| | --Inorganics | 0.01 | PEA, Cal-EPA (DTSC, 1994), ADHS SRLs |
| IRAa | Inhalation rate - adult (m$^3$/day) | 20 | Exposure Factors , USEPA 1991 (OSWER No. 9285.6-03) |
| IRAc | Inhalation rate - child (m$^3$/day) | 10 | RAGS (Part A), USEPA 1989 (EPA/540/1-89/002) |
| IRSa | Soil ingestion - adult (mg/day) | 100 | Exposure Factors, USEPA 1991 (OSWER No. 9285.6-03) |
| IRSc | Soil ingestion - child (mg/day), | 200 | Exposure Factors, USEPA 1991 (OSWER No. 9285.6-03) |
| EFr | Exposure frequency - residential (d/y) | 350 | Exposure Factors, USEPA 1991 (OSWER No. 9285.6-03) |
| EDr | Exposure duration - residential (years) | 30$^c$ | Exposure Factors, USEPA 1991 (OSWER No. 9285.6-03) |
| | Exposure duration - child (years) | 6 | Exposure Factors, USEPA 1991 (OSWER No. 9285.6-03) |
| | Age-adjusted factors for carcinogens: | | |
| IFSadj | Ingestion factor, soils ([mg!yr]/[kg!d]) | 114 | RAGS(Part B), USEPA 1991 (OSWER No. 9285.7-01B) |
| IFSADJ | Skin contact factor, soils ([mg!yr]/[kg!d]) | 503 | By analogy to RAGS (Part B) |
| InhFadj | Inhalation factor ([m$^3$!yr]/[kg!d]) | 11 | By analogy to RAGS (Part B) |
| PEF | Particulate emission factor (m$^3$/kg) | 1.396 x 10$^{+9}$ | Soil Screening Guidance (USEPA 1996a) |

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### 3.5 Uncertainties in the Exposure Assessment

All exposure parameters were chosen to produce conservative estimates of total risk from exposure to contaminants.

Exposures calculated from soil were not measured, but were modeled using a conservative methodology shown in Equation 3.2. The major modeling efforts in this assessment are related to the accumulation of the COCs in soils following the application of Ironite® . It should be recognized that when a model is used the uncertainty of the estimated quantities is greater than if an accurate measurement were taken. Modeling creates uncertainties in the exposure analysis, however, due to the conservative models used, actual exposure is likely to be less than that estimated here.

All exposure parameters were chosen to produce conservative estimates of total risk from exposures to contaminants. Exposure concentrations used in the calculation of reasonable maximum intakes are upper-bound estimates.

Soils beneath shrubs and trees where Ironite® has been applied would likely be exposed and available for human contact, however, the fraction of soil actually ingested from the areas where the product has been applied is likely to be much less than 100%. Nevertheless, for the purposes of this screening level analysis, 100% of the soils ingested on a daily basis were assumed to be from the applied area. In addition, soils underneath lawns would likely be unavailable for direct contact since the physical presence of the grass would prevent soils from being exposed. Nevertheless, this risk assessment assumes that these soils represent a potentially complete exposure pathway.

Exposure doses (CDI) used in the calculation of carcinogenic risks and noncarcinogenic hazard quotients are also included in the risk calculation worksheets in the Appendix. These doses are based on the assumptions and calculations shown in previous sections. They may be considered screening-level, upper-bound estimates. The estimated doses are used with slope factors (carcinogenic risk calculations) and reference doses (noncarcinogenic calculations) to produce probability estimates of carcinogenic risk, and hazard quotients for noncarcinogenic adverse health effects.

# 4.0 TOXICITY ASSESSMENT

The toxicological information on the chemicals of concern for this study is summarized in this chapter. Emphasis is placed upon the non-carcinogenic and carcinogenic effects with discussions on the dose-response variables (reference dose, slope factor) used in the statement of risk. Each chemical is summarized with regard to use, interactions with other chemicals, exposure routes, toxicokinetics, toxic (health) affects, and carcinogenicity. Detailed toxicological profiles for each COC are included in the Appendix.

## 4.1 Dose-Response Variable for Non-Carcinogenic Effects

The reference dose (RfD) is used as a dose-response variable for assessing the non-carcinogenic effects of exposure to chemicals. The chronic RfD is used in calculating the risk of long-term exposure to specific chemicals. USEPA defines the chronic reference dose as "an estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. Chronic RfDs are specifically developed to be protective for long-term exposure to a compound." (RAGS). The USEPA derives the RfDs from animal and, when available, human studies by taking the highest dose at which no adverse effect is seen (NOAEL or no-observed-adverse-effect level) and dividing it by the product of the uncertainty factor (UF) and modifying factor (MF) as shown in the formula below (1). The UF is usually 10 or factors of 10 and estimates the uncertainty in the data from which the NOAEL is derived, especially if it is obtained from animal studies. The MF usually ranges from 0 to 10 and suggests further uncertainty as judged by the professional.

The RfD is measured in mg/kg-day and assumes a threshold or level of exposure at which no adverse health effect will be seen. Although the subchronic RfD is available for short-term exposures, the chronic RfD is used in this study to measure the long-term, non-carcinogenic effect from exposure to the chemicals of concern. The noncarcinogenic hazard quotient (HQ) is computed by dividing the exposure level for the chemical of concern by the specific RfD for that chemical. The noncarcinogenic hazard index (HI) is computed by summing the HQ for individual chemicals for an exposure pathway and represents an estimate of the total hazard for that pathway. Adverse health effects may occur when the HQ or HI exceeds one. RfDs for non-carcinogenic toxicity were obtained from the USEPA on-line Integrated Risk Information System (IRIS) database, and the USEPA Health Effects Assessment Summary Tables (HEAST), FY-1997. Table 4-1 displays RfDs for the COCs.

**Table 4.1: Reference Dose (RfD) for Ingestion and Inhalation**

| Chemical | Inhalation RfD (mg/kg-d) | Ingestion RfD (mg/kg-d) | Sensitive Organs and Systems Affected | RfC/RfD Source |
|---|---|---|---|---|
| **Arsenic** | 3.0E - 04 | 3.0E - 04 | Neurological / Blood, Immune, Neurological, Respiratory, Skin | IRIS/IRIS |
| **Cadmium** | 5.7E - 05 | 5.0 E - 04 | Respiratory, Renal, Hepatic/Gastrointestinal, Renal, Musculoskeletal | IRIS/IRIS |
| **Lead** | N/A | N/A | Hepatic, Immunological/Hematological, Renal, Musculoskeletal | IRIS/IRIS |

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### 4.2 Dose-Response Variable for Carcinogenic Effects

The slope factor (SF) is utilized as the dose-response variable for assessing the carcinogenic effects of exposure to chemicals. USEPA defines the slope factor as "a plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen." (USEPA, 1989). The SF is an estimate of the quantitative relationship between dose and carcinogenic response.

The SF is measured in units of $(mg/kg\text{-}day)^{-1}$ and is usually determined using the upper 95 percent confidence limit of the slope of the linearized multi-stage model. The model assumes that there is no threshold for the initiation of cancer (i.e. any exposure poses a risk of cancer). Since data on carcinogenicity is often derived from high-dose experiments on animals, extrapolations are made from these high doses to lower doses. When available, human data are used to determine the slope factor. Excess cancer risk is expressed as a function of exposure and is calculated by multiplying an estimated dose of a chemical by the slope factor (SF). The application of the nonthreshold assumption and the use of the upper 95 percent confidence limit for estimating the slope factor provides a conservative estimate of potential carcinogenic risk.

From human and animal experimental data, the USEPA's Carcinogen Advisory Group has grouped chemicals by weight-of-evidence (WoE) into classes from A to E which designate their potential as a cancer-causing agent. The WoE represents the carcinogenicity evidence from human and animal studies and indicates the strength of the data. An A classification signifies that the chemical is a proven human carcinogen. Probable human carcinogens are designated either B1, showing that studies in humans are strongly suggestive but not conclusive, or B2 if the chemical has been conclusively carcinogenic in repeated animal studies but not conclusive in human studies. A chemical may be classified C, a possible human carcinogen, if a single high-quality animal study or several low-quality animal studies indicate carcinogenicity. If there is insufficient human and animal evidence to determine the carcinogenicity of the chemical, it is classified as D. A chemical conclusively demonstrated to be non-carcinogenic to humans is in group E. This designation is rare due to the difficulty in producing the necessary negative data.

RfDs for non-carcinogenic toxicity and slope factors for carcinogenic toxicity were obtained from the USEPA on-line IRIS database, and the USEPA Health Effects Assessment Summary Tables HEAST, FY-1997.

**Table 4.2: Slope Factor (SF) for Carcinogenic Chemicals of Concern**

| Chemical | WoE[1] | Slope Factor/Unit Risk[1] | | Type of Cancer | Study Source of SF |
|---|---|---|---|---|---|
| | | Inhalation (mg/kg-day) $^{-1}$ | Ingestion (ug/L) $^{-1}$ [(mg/kg-day)$^{-1}$] | Inhalation / Ingestion | |
| **Arsenic** | A | 15 | 1.5 | lungs/skin | IRIS/IRIS |
| **Cadmium** | B2 | N/A | 6.3 | lungs/skin | N/A/IRIS |
| **Lead** | B2 | N/A | N/A | N/A | NA/NA |

### 4.3 Bioavailability of Arsenic

Adjusting RfDs and SF to account for relative absorption efficiencies may be appropriate if the media of exposure used to derive the toxicity value differs from the absorption efficiency at the site. The oral RfD and oral SF for arsenic have been derived by the USEPA using data from a study in Taiwan where individuals were exposed to dissolved arsenic in water. Inorganic arsenic in solution is highly bioavailable, with most estimates in excess of 95%. The relative bioavailability of the arsenic in Ironite® has not been determined, however, a number of in vivo and in vitro studies have been conducted that suggest that the bioavailability of mineralized arsenic in soils is considerably less that the bioavailability in solution.

In vitro studies of the bioavailability of the As in Ironite® conducted by Washington State University in 1998 (Washington State Department of Ecology, 1998)suggested that under the conditions that may be encountered in the stomachs of individuals, the bioavailability of the As in Ironite is between 21% and 36%, depending upon the pH of the contents of the stomach. A solubility study of Ironite® conducted by Davis (Geomega, 1998) found that at a pH of 3, 2.2% of the As in was solubilized, and 24% of As was solubilized at a pH of 2.

Casteel et al. (Casteel, 1997) examined the relative bioavailability of As in mining wastes in immature swine. The results of their analyses found that the relative bioavailability in the different mining wastes compared with soluble arsenic ranged from near 0% to about 70%. While the authors caution that their results are semi-quantitative, and that there are a number of uncertainties in their analysis, the authors concluded that... "*The relative bioavailability analysis results for different test materials investigated strongly support the view that arsenic in most soils and mine wastes is not as well absorbed as soluble arsenic. Because arsenic in most of the test materials is absorbed less-extensively than soluble forms of arsenic, the use of default toxicity factors for assessing human health risk from soil may lead to an overestimate of hazard. Application of site-specific RBA values is expected to increase the accuracy and decrease the uncertainty in human health risk assessments for arsenic*."

Freeman et al. (Freeman et al, 1995) found that the mean absolute bioavailability of arsenic estimated from urine arsenic concentrations were 91%, 18.3%, and 25.8% following oral administration in cynomolgus monkeys via gavage, soil, and dust respectively. The mean absolute bioavailability estimated from blood arsenic concentrations were between 91 and 100% for gavage, 11 to 18% for soil ingestion, and 8 to 11% for dust. USEPA Region XIII concluded in 1995 that.... "*The study demonstrates that the absorption of arsenic from soils and dust is significantly less than absorption of soluble arsenic from water, and should be used from site-specific adjustments in bioavailability for the Anaconda NPL site*." (USEPA, 1995).

Due to the fact that the arsenic present in Ironite is derived from mining waste, and that A:\TEXT2.WPD the relative absorption efficiency differences between As in water and soils is well documented, the ADHS has used USEPA oral bioavailability estimate for the Anaconda site of 18.3% for this risk assessment.

Since no studies were found suggesting that the bioavailability via inhalation and dermal contact is limited by these exposure routes, bioavailability adjustments have not been made for these exposure routes.

### 4.4 Lead

The threshold for the systemic toxic effects from exposure to lead in soils were evaluated using the USEPA IEUBK model for estimating exposures to lead. The criteria used to determine an unacceptable risk to children used in this analysis is the United States Center for Disease Control and Prevention (CDC) objective to limit to 5% the percentage of children with blood lead levels in excess of 10 $\mu$g/dL. These criteria are also based upon recommendations by the USEPA and that there be no more than a 5% likelihood that a child exceeds a blood lead level of 10 $\mu$g/dL.

The residential Arizona SRL of 400 mg/kg represents a concentration of lead in soil that would be expected to limit to 5% the percentage of children with blood lead levels greater than the reportable limit of 10 $\mu$g/dL. The nonresidential SRL of 2000 mg/kg represents a concentration of lead in soil that would be expected to limit to 5% the percentage of babies born with blood lead levels greater than 10 $\mu$g/dL in the exposed maternal population.

# 5.0 RISK CHARACTERIZATION

Inhalation risks from subsurface soil contamination are evaluated in this chapter using exposure and toxicology information previously discussed. The risk characterization is presented in a quantitative and qualitative format.

## 5.1 Risk Estimation Methods

Risk estimation methods used in this report were based on USEPA guidelines. Potentially complete exposure pathways for this analysis include direct and indirect contact with soils that may become contaminated over time. The methods used to evaluate exposure and toxicity are conservative and tend to overestimate risk.

### 5.1.1 Calculation of Carcinogenic Risk

Carcinogenic risk is calculated as the incremental probability of an individual developing cancer over a lifetime (70 years), due to exposure to a carcinogenic compound. This is also referred to as incremental or excess lifetime cancer risk (ELCR) and represents the increased risk of developing cancer above the background rate, estimated to be about 3E-1 (30%).

Estimates of ELCR were based on calculations developed in the following order. Information on exposure pathways, exposure concentrations, and toxicology was assembled or calculated. The CDIs were then calculated using assumptions from the exposure and toxicity reviews presented in Chapters 3 and 4. Chemical specific carcinogenic SF, were used to convert estimated CDI, averaged over a lifetime, to ELCR.

The dose-response relationship is considered to be linear under the low dose conditions usually encountered in environmental exposures. Under this assumption, the SF is a constant, and risk is directly related to intake. Therefore, the linear low-dose cancer risk equation is:

$$\text{Risk} = \text{CDI} \times \text{SF}$$

where:

Risk=a unitless probability of an individual developing cancer;

CDI = Chronic daily intake (dose) averaged over 70 years (mg/kg-day);

SF = Slope Factor, expressed in $(\text{mg/kg-day})^{-1}$.

The SF usually represents an upper 95$^{th}$ percentile confidence limit of the probability of response, based on experimental animal data. Therefore, the risk estimate will also be an upper-bound estimate and *true risk* is likely to be less than predicted by this model.

For known or suspected carcinogens, the USEPA considers exposure levels that present an excess lifetime cancer risk to an individual of between 1E-4 to 1E-6 to be within the acceptable range of risk. Risk estimates less than 1E-6 (one-in-one-million) are considered negligible.

### 5.1.2 Noncarcinogenic Effects

Noncarcinogenic effects include neurotoxic, hepatoxic, nephrotoxic, teratogenic, reproductive reactions, and any other noncancer related systemic toxic responses. The potential for an individual suffering a noncarcinogenic effect is not expressed as a probability, but as a ratio or quotient. The hazard quotient (HQ) is the ratio of an exposure level over a specified period (CDI) to the chemical specific RfD which is not expected to produce toxic effects over the period of concern. The HQ is calculated as follows:

Noncancer Hazard Quotient = CDI/RfD
CDI = Daily intake (dose) in mg/kg-day;
RfD = reference dose in mg/kg-day.

*The HQ is not expressed as a probability.* If the HQ exceeds 1 the possibility that exposed individuals may experience adverse health effects cannot be ruled out. The higher the HQ, the greater the concern. Effects can be evaluated over three time periods; short term, usually less than 2 weeks (acute), 2 weeks to 7 years (subchronic), and more than 7 years (chronic). In this assessment only chronic exposures were evaluated.

### 5.2 Risk Characterization

ELCR and HQ estimates were made in order to evaluate the potential health risks that may be presented by direct contact with residential soils under lawns and shrubs that may become contaminated with potential COCs following prolonged use of Ironite® . The analysis evaluates the potential for both cancer and systemic toxicity to adult and child residential carcinogenicity in residential receptors. Ingestion, inhalation, and dermal contact with soils were quantified.

Soils beneath shrubs and trees where Ironite® has been applied would likely be exposed and available for human contact, however, the fraction of soil actually ingested from the areas where the product has been applied is likely to be much less than 100%. Nevertheless, for the purposes of this analysis, 100% of the soils ingested on a daily basis were assumed to be from the applied area. In addition, soils underneath lawns would likely be unavailable for direct contact since the physical presence of the grass would prevent soils from being exposed. Nevertheless, this risk assessment assumes that these soils represent a potentially complete exposure pathway.

### 5.2.1 Carcinogenicity

The reasonable maximum ELCR estimate from exposure to contaminants that may accumulate in soils underneath lawns following prolonged application of Ironite® in a residential setting is estimated to be 3E-5 (three-in-one-hundred-thousand). The reasonable maximum ELCR estimate from exposure to contaminants that may accumulate in soils underneath shrubbery and trees following prolonged application of Ironite® in a residential setting is estimated to be 2E-5 (two-in-one-hundred-thousand). Both of these risk estimates are within the acceptable range of risk established by the USEPA.

Virtually all of the ELCR estimate for both exposure areas would be expected to be due to the accumulation of arsenic. The risk estimates integrate childhood and adult exposure to the COCs over a 30-year exposure interval. The estimate includes direct contact with soils via ingestion, inhalation and dermal contact.

### 5.2.2 Systemic Toxicity

The reasonable maximum Hazard Quotient (HQ) from exposure to contaminants that may accumulate in soils underneath lawns and shrubbery following prolonged application of Ironite® in a residential setting is estimated to be less than 1 for both children and adults. The USEPA IEUBK model was used to evaluate the potential systemic hazard for lead since the USEPA has not established a reference dose for this metal. The criteria used to determine an unacceptable risk to children used in this analysis is the CDC objective to limit to 5% the percentage of children with blood lead levels in excess of 10 $\mu$g/dL. These criteria are also used by the USEPA. The results of the IEUBK analysis suggest that the accumulation of lead in soils from the use of Ironite® may contribute to the total amount of lead exposure in children such that less than 1% of those exposed would be expected to have blood lead levels in excess of the 10 $\mu$g/dL reportable limit.

These estimates suggest that no systemic toxicity threat would be presented to either children or adults following prolonged use as suggested on the label on lawns or shrubbery.

### 5.3 Summary

The objective of this risk assessment is to provide an evaluation of health risks that may result from exposure to soils that may become contaminated with metals present in Ironite® following long-term application as directed in a residential setting.

This report evaluates the potential for chronic systemic toxicity and carcinogenicity in child and adult residential receptors. The analysis considers exposures via ingestion, inhalation, and dermal contact. The report does not consider exposures that may occur as a result of the potential uptake of contaminants into terrestrial garden plants and trees.

The risk assessment is written using a deterministic methodology that is consistent with current risk assessment guidance issued by the USEPA. Chemicals of concern are selected using USEPA and ADHS risk assessment guidance. Exposures are quantified assuming reasonable maximum exposure assumptions that incorporate USEPA standard default exposure factors. Exposure concentrations are modeled assuming that the product is used as suggested on the label for 30 years. Toxicity is assessed using current USEPA cancer slope factors and reference doses and CDC recommendations for the maximum percentage of children with blood lead levels in excess of 10 $\mu$g/dL. Incremental risks and noncancer hazards are quantitatively and qualitatively evaluated.

Arsenic, cadmium and lead were selected as the potential COCs in Ironite® . The concentration of the COCs that may be present in surface soils following long term application of Ironite® were modeled using a conservative methodology that assumes that Ironite® is applied as suggested on the label. Modeling was conducted using USEPA equations and assumptions. Area specific values were used where necessary. The potentially complete exposure route to the potential COCs in surface soil include ingestion, dermal contact, and inhalation of fugitive dust.

Soils beneath shrubs and trees where Ironite® has been applied would likely be exposed and available for human contact, however the fraction of soil actually ingested from the areas where the product has been applied is likely to be much less than 100%. Nevertheless, for the purposes of this analysis, 100% of the soils ingested on a daily basis were assumed to be from the applied area. In addition, soils underneath lawns would likely be unavailable for direct contact since the physical presence of the grass would prevent soils from being exposed. Nevertheless, this risk assessment assumes that these soils represent a potentially complete exposure pathway.

The reasonable maximum ELCR estimate from exposure to contaminants that may accumulate in soils underneath lawns following prolonged application of Ironite® in a residential setting is estimated to be 3E-5 (three-in-one-hundred-thousand). The reasonable maximum ELCR estimate from exposure to contaminants that may accumulate in soils underneath shrubbery following prolonged application of Ironite® in a residential setting is estimated to be 2E-5 (two-in-one-hundred-thousand). Both of these risk estimates are within the acceptable range of risk established by the USEPA.

The reasonable maximum Hazard Quotient (HQ) from exposure to contaminants that may accumulate in soils underneath lawns, shrubs and trees following prolonged application of Ironite® in a residential setting is estimated to be less than 1 for both children and adults. The USEPA IEUBK model was used to evaluate the potential systemic hazard for lead since the USEPA has not established a reference dose for this metal. The results of the IEUBK analysis suggest that the accumulation of lead in soils from the use of Ironite® as directed would not represent a health threat to children living in homes where it is applied.

In summary, the cancer risk level for integrated residential exposure to metals that may accumulate in residential soils following long-term use of Ironite® is within the acceptable range of risk according to the USEPA. The study also suggests that maximal residential childhood exposure to metals that may accumulate in residential soils following long-term use of Ironite® would be below levels that would result in adverse noncancer health effects.

This report does not consider exposures that may occur as a result of the potential uptake of contaminants into terrestrial garden plants and trees. The analysis also does not consider the potential for adverse health effects as a result of direct contact with the product during application.

### 5.4 Uncertainties in the Risk Assessment

All exposure parameters were chosen to produce conservative estimates of total risk from exposure to contaminants. Exposures calculated from soil were not measured, but were modeled using a conservative methodology shown in Equation 3.2. The major modeling efforts in this assessment are related to the accumulation of the COCs in soils following the application of Ironite® . It should be recognized that when a model is used the uncertainty of the estimated quantities is greater than if an accurate measurement were taken. Modeling creates uncertainties in the exposure analysis, however, due to the conservative models used, actual exposure is likely to be less than that estimated here.

All exposure parameters were chosen to produce conservative estimates of total risk from exposures to contaminants. Exposure concentrations used in the calculation of reasonable maximum intakes are upper-bound estimates.

Soils beneath shrubs and trees where Ironite® has been applied would likely be exposed and available for human contact, however, the fraction of soil actually ingested from the areas where the product has been applied is likely to be much less than 100%. Nevertheless, for the purposes of this screening level analysis, 100% of the soils ingested on a daily basis were assumed to be from the applied area. In addition, soils underneath lawns would likely be unavailable for direct contact since the physical presence of the grass would prevent soils from being exposed. This risk assessment assumes that these soils represent a potentially complete exposure pathway.

Exposure doses (CDI) used in the calculation of carcinogenic risks and noncarcinogenic hazard quotients are also included in the risk calculation worksheets in the Appendix. These doses are based on the assumptions and calculations shown in previous sections. They may be considered screening-level, upper-bound estimates. The estimated doses are used with slope factors (carcinogenic risk calculations) and reference doses (noncarcinogenic calculations) to produce probability estimates of carcinogenic risk, and hazard quotients for noncarcinogenic adverse health effects.

### 5.4 Conclusion

The accumulation of metals that may occur following prolonged use of Ironite® in a residential setting does not appear to represent a health risk to adult or child residents of homes where it is used if the product is applied in accordance with recommendations on the label.

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