Dermal Contact With Soil

PIONEER Technologies Corporation – http://www.uspioneer.com
December 2001

Note: The United States Environmental Protection Agency (USEPA) is currently preparing a new guidance document for evaluating dermal exposure. Because this document is in the process of peer review and revision, it is not yet approved for use. Therefore, the information presented in this paper is based on the current dermal guidance document (i.e., USEPA, 1992. Dermal Exposure Assessment: Principles and Applications) (USEPA, 1992). As a preview to risk managers and risk assessors, an overview of the proposed approach for evaluating dermal exposure in the new guidance document is presented in Section 6 of this issue paper.

Executive Summary

Regulatory agencies are beginning to regularly require quantitative evaluation of dermal exposure in risk assessments and in the development of risk-based screening concentrations (RBSCs). Recent studies have furthered the science of estimating dermal exposure, however there is still a large amount of uncertainty associated with calculating exposure and risks because of the lack of empirical data for key parameters. Consequently, agencies have employed "default" values to calculate dermal risks. These values often incorporate conservative safety factors and are highly uncertain. In order to adequately address this uncertainty, it is recommended that empirical data be used when possible as the basis for all input parameters when evaluating dermal exposure.

Key Issues and Concepts

- ☑ The methods currently used for evaluating health risks related to the dermal route of exposure are very conservative, and often lead to risk estimates which are higher than those for other exposure pathways. Consequently, a cleanup decision for a site may be driven by risks estimated for the dermal pathway.

- ☑ A qualitative (as opposed to quantitative) evaluation of dermal exposure should be performed whenever possible. If a quantitative evaluation is required, use assumptions based on empirical data rather than default or modeled values.

- ☑ Ensure that dermal toxicity values are appropriate. Dermal toxicity values are derived from oral toxicity values via route-to-route extrapolation by adjusting for gastrointestinal (GI) absorption. Ensure that dermal toxicity values derived from oral toxicity values are adjusted for GI absorption only when convincing scientific evidence (empirical data) suggests that GI absorption is less than 100%. Use of dermal toxicity values adjusted for GI absorption will increase the resultant risk estimates.

- ☑ Do not evaluate volatile organic compounds (VOCs) and inorganic elements via dermal contact with soil.

- ☑ Avoid using overly conservative default soil-to-skin-adherence factors by using empirical data to determine activity and body part specific adherence factors.

- ☑ Consider including the dermal evaluation in the uncertainty/sensitivity analysis section of the risk assessment. This provides risk managers with the information in a manner that recognizes the inherent uncertainty due to the current state of the science.

- ☑ Perform the risk assessment in a manner consistent with USEPA guidance so that the reasonable maximum exposure (RME) scenario is evaluated. This means don't always use maximum values – the final evaluation should be realistic.

- ☑ Risk assessors should articulate the high degree of uncertainty associated with the dermal exposure pathway in the risk assessment. They should also communicate with risk managers to ensure that the results of dermal exposure assessments are placed in proper context.

- ☑ The USEPA explicitly recognizes the shortcomings of the available data for evaluating dermal exposure in the dermal guidance by stating "major uncertainties exist in the extent to which a chemical is percutaneously absorbed (i.e., the chemical is absorbed into the body via the skin) and in the extent to which a chemical will partition from soil to skin (USEPA, 1992)." Recent studies have furthered the science of estimating dermal exposure but there is still a large amount of uncertainty due to the lack of empirical data for key parameters.

1.0 Introduction

Risk assessments of hazardous waste sites typically evaluate exposure to soil via incidental soil ingestion. An additional pathway of exposure that is being increasingly evaluated is dermal contact with soil. Estimating the risks associated with dermal contact with soil is a complex process that relies on a number of factors. For many of these factors there is very little scientifically validated information available. In the absence of empirical data "default values", which are typically conservative assumptions that include safety factors, are incorporated into the calculations. Depending on the assumptions made, including dermal exposure in a risk assessment can have a major impact on the overall risks and the management decisions made at a site. This paper focuses on three factors that have the most significant impact on the uncertainties associated with evaluating dermal exposure to soil:

1. **Dermal Toxicity Values** – Deriving dermal toxicity values from oral toxicity values via route-to-route extrapolation.

2. **Dermal Absorption Values** – The amount of chemical that penetrates the skin and enters the bloodstream.

3. **Soil-to-Skin-Adherence Factors** – The amount of soil that adheres to the skin.

There are large data gaps for each of these three factors that are discussed in greater detail below. In addition, there are other factors that are uncertain including the area of skin exposed during each contact event, duration of soil adherence to skin, frequency of skin contact with soil, and the potential metabolism of constituents within the skin layers (USEPA, 2000). Despite these complicating factors, dermal uptake of contaminants from soil is typically modeled primarily as a function of soil adherence and dermal absorption factors.

2.0 Dermal Toxicity Values

Toxicity values are used in conjunction with exposure information to evaluate the potential for noncarcinogenic health effects and cancer risks. For dermal exposure however, the USEPA has not developed toxicity values specifically for evaluating potential human health concerns. Most of the available toxicological criteria have been derived for the oral route of exposure, while criteria for the inhalation route of exposure are available for limited number of chemicals. Therefore, an interim decision was made by the Superfund program to estimate dermal toxicity criteria based on existing oral criteria (i.e., route-to-route extrapolation).

Most exposure pathways, such as incidental soil ingestion, quantify exposure based on the amount of chemical that an individual comes in contact with on a daily basis (i.e., intake). The toxicity values used to evaluate the risks associated with these exposure pathways are typically consistent with this approach

in that they are also developed based on intake (often referred to by toxicologists as administered dose). In contrast, dermal exposure is determined based on the amount of chemical that penetrates the skin and is absorbed into the blood stream. Consequently, toxicity values based on administered dose should technically be adjusted to reflect the absorbed dose when evaluating the risks associated with dermal exposure.

The approach developed by USEPA to derive dermal toxicity values from oral toxicity values adjusts the administered dose based on how much of the chemical was absorbed in the gastrointestinal (GI) tract. Ideally the amount of GI absorption would be measured in the original oral toxicity study. However, this is rarely done. In the absence of study-specific GI absorption factors, factors are obtained from the scientific literature. Unfortunately, conservative default values are usually selected because of the paucity of information about GI absorption. In addition, the current approach for developing GI absorption values does not take into account the method of administration (e.g., gavage, drinking water, or diet) in the original study or the vehicle of administration (e.g., solvent, oil, or solution, et cetera), which may significantly impact the GI absorption rate. It is unlikely that the resulting GI absorption rate is representative of the rate that would be found for the same chemical in soil. The current method recommended by the USEPA for converting toxicity values from administered to absorbed dose relies on the following assumptions:

- Health effects following exposure are not route-specific. This assumption ignores potential differences in metabolism of a constituent absorbed through ingestion vs. dermal contact.

- Portal-of-entry effects (e.g., dermatitis associated with dermal exposure and respiratory effects associated with inhalation exposure) are not the principle effects of concern. For example, the USEPA recommends that the current default approach for deriving dermal toxicity values is inappropriate for carcinogenic polycylic aromatic hydrocarbons (PAHs), because this group of compounds causes skin cancer through direct action at the point of application (e.g., portal-of-entry effects) (USEPA, 1989). The USEPA further recommends that risks from dermal exposure to these compounds be qualitatively evaluated (USEPA, 1989).

Conclusions and Recommendations

There is an inverse relationship between GI absorption and estimated dermal risks. That is, as the GI absorption factor decreases, the calculated dermal risks increase. Consequently, oral toxicity values should only be adjusted when there are convincing empirical data that suggest that GI absorption is less than 100%. While this is less conservative than assuming a default value for GI absorption, it eliminates the problem of incorporating overly conservative values in the absence of good data. This approach is consistent with USEPA guidance. USEPA recommends that the Environmental Criteria and Assessment Office (ECAO) be contacted for guidance on adjusting oral toxicity values to derive dermal toxicity values. In the absence of information from ECAO, USEPA recommends that "the assessor should describe the effects of the chemical qualitatively and discuss the implications of the absence of the chemical from the risk estimated in the uncertainty section of the risk assessment (USEPA, 1989)." Furthermore, USEPA's Dermal Exposure Assessment: Principles and Applications states that, "...if estimates of the gastrointestinal absorption fraction are available for the compound of interest in the appropriate vehicle, then the oral dose-response factor, unadjusted for absorption, can be converted to an absorbed dose basis..." and "Lacking this information, the oral factor should be used as is accompanied by a strong statement emphasizing the uncertainty involved (USEPA, 1992)."

3.0 Dermal Absorption Values

Another key consideration when evaluating dermal exposure is determining the degree to which chemicals penetrate the skin and are absorbed into the bloodstream. Determining the rate and amount of percutaneous absorption of a chemical is very complex and depends on numerous factors including the physiological characteristics of the skin (e.g., skin thickness, hydration, temperature) and the physio-chemical nature of the chemical contacting the skin (e.g., lipophilicity, polarity, volatility). In addition, the vehicle of administration (e.g., soil, water, sediment) may increase or decrease the percutaneous

absorption rate. For example, chemicals in soil are typically bound to particles and/or organic matter. In order for chemicals to be absorbed by the skin, they must first be desorbed from soil. This competing process may reduce the rate and amount of absorption.

The two primary approaches for determining dermal absorption rates are models and laboratory experiments. The modeling approach is based on evaluating the relationship between the physiological characteristics of the skin and the physio-chemical properties of the chemical being studied. In most cases the models overestimate the percutaneous absorption rates because they are simplistic and do not reflect the myriad of exposure conditions and competing processes encountered in environmental settings. For example, researchers have attempted to establish a relationship between the octanol: water partition coefficient (log $K_{o/w}$) and the percutaneous absorption rate. Until the early 1990's the use of this relationship was a widely accepted approach for developing percutaneous absorption rates for use Superfund Health Risk Assessments. However, this approach has lost favor and as stated in the Dermal Exposure Assessment: Principles and Applications, "...it appears that the log $K_{o/w}$ may not always properly reflect the lipophilicity of certain classes of chemicals, and thus, may be an inconsistent predictor of skin permeability (USEPA, 1992).

Many of the "default" dermal absorption values recommended by USEPA are based on the results of laboratory experiments that are not conducted in a manner consistent with environmental exposure conditions. For example, many studies evaluating dermal absorption dissolve the chemical in a solvent, apply it directly to the skin, wrap the contact area with bandages to prevent evaporation, and leave the area undisturbed for hours. This is clearly in contrast with typical exposure conditions where individuals rarely come in direct contact with the pure form of a chemical, evaporation does occur and the contact area is typically disturbed (e.g., washing hands). All of these factors tend to mitigate exposure.

Conclusions and Recommendations

The conclusions and recommendations presented below are based on information presented in USEPA's *Dermal Exposure Assessment: Principles and Applications* (USEPA, 1992).

- The skin acts as a barrier to dermal absorption for most chemicals.
- Experimentally derived percutaneous absorption factors, based on soil applications of 0.2 to 1.0 mg/cm^2, are available for only a few constituents (e.g., polychlorinated dibenzo-p-dioxins (dioxins) 3%, polychlorinated biphenyls (PCBs) 6%, and tetrachlorobiphenyl 6%).
- Dermal absorption values used in human health risk assessments should be based on chemical-specific empirical data obtained from studies that are representative of actual environmental exposures.
- If chemical-specific data are not available, which is typically the case, dermal absorption values from a related chemical (e.g., same class) should be used as a surrogate.
- If there are no chemical-specific dermal absorption rates available for a related chemical then the highest dermal absorption rate observed for all organic chemicals should be used as a surrogate value. For example, a default value of 6% could be assumed for organic constituents lacking empirically derived chemical-specific dermal absorption data. This value reflects the highest empirically derived percutaneous absorption rate for all organic constituents evaluated with soil applications from 0.2 to 1.0 mg/cm^2 and exposure durations less than 24 hours (USEPA, 1992).
- Dermal absorption of VOCs from soil should not be evaluated because, at soil-loading rates of 1.0 mg/cm^2 or less, volatilization is expected to negate dermal absorption.
- Dermal absorption of inorganic elements from soil should not be evaluated; their absorption potential is considered negligible (i.e., <1 percent).

- Dermal exposure to polycyclic aromatic hydrocarbons (PAHs) or other chemicals that exhibit portal-of-entry effects should be qualitatively (not quantitatively) evaluated in the risk assessment (USEPA, 1989).

4.0 Soil-To-Skin Adherence Factors

In order to have exposure to chemicals via dermal contact, it is necessary for soil to adhere to the skin. The soil-to-skin adherence factor is a measure of how much soil adheres to the skin. The more soil that adheres to the skin the higher the potential for exposure. The results from studies on soil-to-skin adherence suggest that:

- Adherence levels vary with activity.
- Adherence levels vary considerably across different parts of the body.
- Soil properties influence adherence. Adherence increases with moisture content and decreases with particle size, but is relatively unaffected by clay or organic carbon content.

Typically these determinants of soil adherence to skin are ignored and adherence factors are represented by default values. Recent studies have evaluated soil adherence to skin for different activity patterns, parts of the body, and soil types. Although these data are limited they are a step in the right direction.

The USEPA Exposure Factors Handbook summarizes the latest information available in the scientific literature on adherence factors and concludes that the information presented in the handbook are, "...based on limited data. Therefore, they have a high degree of uncertainty such that considerable judgment must be used when selecting them for an assessment (USEPA, 1996)." In addition, USEPA states that "the overall rating for the exposure factor is low because of limited data which makes it difficult to extrapolate from experiments and field observations to general conditions (USEPA, 1996)."

Conclusions and Recommendations

The activity and body part specific soil-to-skin adherence factors presented in the USEPA Exposure Factors Handbook should be used to develop representative soil-to-skin adherence factors for evaluating dermal contact with soil. Depending on the soil type being assessed, these values are several orders of magnitude lower than the values previously recommended by the USEPA (i.e., 1.45 mg/cm^2 for potting soil and 2.77 mg/cm^2 for kaolin clay) (USEPA, 1989). In addition, there is always the option of developing site-specific adherence factors. This would greatly reduce the uncertainty. However, such an endeavor would likely be very costly and would require significant negotiations with regulators.

5.0 Other Recommendations

5.1 Overall Risk Assessment and Exposure Pathways Should Reflect the RME Scenario

The USEPA recommends that "actions at Superfund sites should be based on an estimate of reasonable maximum exposure (RME) expected to occur under current and future land use conditions (USEPA, 1989)." The USEPA recognizes that "estimates of the RME necessarily involve the use of professional judgment" and identifies the goal of evaluating an RME scenario to be "a conservative exposure case (i.e., well above average) that is still within the range of possible exposures (USEPA, 1989)." This framework is often overlooked when selecting exposure factors for dermal exposure. This objective should be a cornerstone for developing a plausible dermal exposure scenario. In practice this will mean that in some cases upper bound values will be selected for certain parameters while in other cases average values will be selected.

5.2 Include Dermal Risk Calculations as Part of the Sensitivity/Uncertainty Analysis

An effective way to manage the dermal evaluation in the risk assessment process is to evaluate dermal exposure as part of the uncertainty/sensitivity analysis and not as a part of the main risk assessment. In this way the risks for dermal exposure are calculated and presented in the report for review in a suitable context without overemphasizing the dermal route of exposure. This approach could be characterized as semi-quantitative in that risks are calculated but they are not given undo weight, and are not included with the risk calculations in the body of the report.

5.3 Clearly Communicate the Uncertainties Associated With Dermal Exposure

It is important that risk assessors communicate the uncertainties associated with dermal exposure. If a regulator requires a quantitative dermal evaluation then it may be appropriate to perform a sensitivity analysis in order to demonstrate that if reasonable alternative assumptions are used the risks are significantly different. In most cases a Monte Carlo simulation is not appropriate because there are not enough data to develop distributions. In addition, if regulators require a quantitative evaluation, uncertainties associated with the existing methodology and database should be identified and characterized to the extent possible in the risk assessment report.

6.0 Overview of the EPA's Review Draft Superfund Dermal Guidance Document

The purpose of this section is to provide a brief overview of the information that is presented in the USEPA's external review draft document on dermal exposure entitled: *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual Supplemental Guidance Dermal Risk Assessment, INTERIM GUIDANCE* (USEPA, 1998). This document, referred to as the "SDG" document, has not been formally released to the public, however some USEPA Regions (e.g., Region IX) are using information presented in the guidance to evaluate dermal exposure. While the information presented in the SDG is not final USEPA Guidance, it provides Navy Remedial Project Managers (RPMs) with an indication of the direction that the USEPA is heading in regards to evaluating dermal exposure.

Note: The SDG has not formally been released to the public and is Interim Guidance. As such, the policies set out in the document are not final Agency action, but are intended solely as interim guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. USEPA officials may decide to follow the guidance provided in the document, or to act at variance with the guidance, based on an analysis of site-specific circumstances. The Agency also reserves the right to modify this guidance at any time without public notice.

The parameters recommended in the SDG for evaluating dermal exposure to soil are presented below:

- **Dermal Absorption Factors for Soil** (USEPA, 1998) – Table 6-1 presents the Dermal Absorption Factors for soil that are recommended in the SDG.

Table 6-1 — Dermal Absorption Factors Recommended in the SDG (USEPA, 1998)

Compound	Dermal Absorption Factor (for Soil)
Arsenic	0.03
Cadmium	0.01
Chlordane	0.04
2,4-Dichlorophenoxyaceticacid	0.05
DDT	0.03

Table 6-1 — Dermal Absorption Factors Recommended in the SDG (USEPA, 1998)

Compound	Dermal Absorption Factor (for Soil)
Dioxins TCDD <10% organic soil TCDD >10% organic soil	 0.03 0.001
Lindane	0.04
PAHs Benzo(a)pyrene	 0.13
PCBs Aroclor 1254 and 1242	 0.14
Pentachlorophenol	0.25
Generic Default Values for Screening	
Semivolatile organic compounds	0.1
Inorganics	0.01

- **Skin Surface Areas** (USEPA, 1998)– The recommended skin surface area for adult residents is 5,700 cm^2 (central tendency) to 6,600 cm^2 (upper bound). This is based on an adult wearing a short-sleeved shirt, shorts, and shoes and evaluates exposure to the head, hands, forearms, and lower legs. The recommended skin surface area for child residents is 2,900 cm^2 (central tendency) to 3,400 cm^2 (upper bound). This is based on a child wearing a short-sleeved shirt, shorts, but no shoes and evaluates exposure to the head, hands, forearms, lower legs, and feet.

- **Soil-to-Skin Adherence Factors** (USEPA, 1998) – The recommended soil-to-skin adherence factor (AF) for adult residents is 0.08 mg/cm^2-event. The recommended AF for child residents is 0.3 mg/cm^2-event (central tendency) to 1 mg/cm^2-event (upper bound).

- **Derivation of Dermal Toxicity Values** (USEPA, 1998) – The SDG recommends deriving dermal toxicity values from oral toxicity values when the following conditions are met:

  1. The critical study upon which the toxicity is based employed an administered dose (e.g., delivery in diet or by gavage) in its study design.

  2. A scientifically defensible database exists and demonstrates that the gastrointestinal absorption of the chemical in question from a media (e.g., water, feed) similar to the one employed in the critical study is significantly less than 100% (e.g., < 50%). A cutoff of 50% GI absorption is recommended to reflect the intrinsic variability in the analysis of absorption studies.

  In the event that the aforementioned criteria are not met, it is recommended that a default value of complete (i.e., 100%) oral absorption be assumed, thereby eliminating the need for oral toxicity-value adjustment.

7.0 Other Sources of Information

USEPA. 1992. Dermal Exposure Assessment: Principles and Applications. USEPA/600/8-91/011B. Office of Health and Environmental Assessment. Washington, DC. http://www.epa.gov/nceawww1/pdfs/derexp.pdf.

USEPA. 1996. Exposure Factors Handbook: Volume I - General Factors. Update to Exposure Factors Handbook USEPA/600/8-89/043 - May 1989 PRELIMINARY DRAFT. Office of Research and Development National Center for Environmental Assessment. Washington, DC 20460. http://www.epa.gov/ncea/exposfac.htm.

USEPA Region III Technical Guidance Manual Risk Assessment: Assessing Dermal Exposure from Soil. http://www.epa.gov/reg3hwmd/risk/solabsg2.htm.

USEPA. 1989. Risk Assessment Guidance for Superfund: Volume 1 – Human Health Evaluation Manual Part A. Interim Final. Office of Emergency and Remedial Response. Washington, DC. 9285.701A. USEPA/540/1-89/002. http://www.epa.gov/superfund/programs/risk/ragsa/index.htm.

7.1 References

USEPA. 2000. Summary Report for the Workshop on Issues Associated with Dermal Exposure and Uptake. EPA/630/R-00/003. Risk Assessment Forum. Washington, DC 20460.

USEPA. 1996. Exposure Factors Handbook: Volume I - General Factors. Update to Exposure Factors Handbook USEPA/600/8-89/043 - May 1989 PRELIMINARY DRAFT. Office of Research and Development National Center for Environmental Assessment. Washington, DC 20460. http://www.epa.gov/ncea/exposfac.htm.

USEPA. 1992. Dermal Exposure Assessment: Principles and Applications. USEPA/600/8-91/011B. Office of Health and Environmental Assessment. Washington, DC. http://www.epa.gov/nceawww1/pdfs/derexp.pdf.

USEPA Region III Technical Guidance Manual Risk Assessment: Assessing Dermal Exposure from Soil. http://www.USEPA.gov/reg3hwmd/risk/solabsg2.htm.

USEPA. 1989. Risk Assessment Guidance for Superfund: Volume 1 – Human Health Evaluation Manual Part A. Interim Final. Office of Emergency and Remedial Response. Washington, DC. 9285.701A. USEPA/540/1-89/002. http://www.epa.gov/superfund/programs/risk/ragsa/index.htm.

USEPA. 1998. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual Supplemental Guidance Dermal Risk Assessment, INTERIM GUIDANCE.