http://www.epa.gov/oswer/riskassessment/ragse/

EPA United States Environmental Protection Agency

Waste and Cleanup Risk Assessment

Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim

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Risk Assessment Guidance for Superfund

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Background

The U.S. Environmental Protection Agency (EPA) developed Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) ("Part E") to address human health risk related to dermal exposures. Parts A, B, C and D of RAGS address other aspects of a human health risk assessment on a Superfund site.

Part E uses a consistent methodology for assessing the exposures from the dermal pathway for Superfund human health risk assessments. It incorporates and updates principles of the EPA (1992) interim report, "Dermal Exposure Assessment: Principles and Applications". Part E does not address dermal exposure to vapors.

Development and Availability

After completing peer review of the guidance, EPA released a draft of Part E for comment in December 2001. In August 2004 EPA released the final guidance on this website.

Errata in the final July 2004 Part E guidance have been corrected in the files available on this website. Corrections were made to the following pages of the guidance:
Page 3-2 (replaced the erroneous symbol for lag time with tau).
Page 3-7 Equation 3.8 (restored "- 0.0056 MW" to the equation line).

Page 3-7 Equations 3.9 and 3.10 presented boundaries of the effective predictive domain, and contained an incorrect numeric value. The incorrect value of 0.5103 was corrected to 5.103. (a 2007 correction)

Page 3-20 Section 3.3 had a discussion of wet vs dry weight sediment data in the 2nd bullet. This discussion has been corrected. (a 2007 correction)

Page A-3 of Appendix A had the incorrect value of 0.5103 in equations 3.9 and 3.10. The corrected value is 5.103. (a 2007 correction)
Page A-6 Exhibit A-2 (corrected the misspelling of phenanthrene).
Page A-12 (replaced the erroneous symbol for lag time with tau).
Page A-14 Exhibit A-4 (changed 0.034 to 0.34).
Page A-15 (modified bold type for exhibit footnote).

Page A-30 Equation A.17 of Appendix A has been corrected to include $Kp > 1.9 \times 10^{-4} ABS_{GI}$. ABS_{GI} in this equation should be expressed as a percent. (a 2007 correction)

Page B-5 Exhibit B-2 of Appendix B: Measured Kp values for benzene, chloroform, tetrachloroethylene and trichloroethylene have become available since RAGS Part E was released in 2004. These Kp values, and their sources, have been added to Exhibit B2. References for other measured Kp values have also been added. (a 2007 addition)

Page B-12 Exhibit B-3 of Appendix B: To clarify some confusion relating to uses of RAGS Part E with respect to contaminants that are outside the effective predictive domain for the water pathway, some "N" symbols were changed to "NA" for "not applicable" to clarify that those contaminants are outside the effective predictive domain. Section 6.3 of RAGS Part E recommends not attempting to quantify risk on such contaminants (outside the effective predictive domain) in the body of a risk assessment. (a 2007 clarification)

Page C-18 Exhibit C-4 of Appendix C: The basis for the presentation of soil particle sizes was changed from the U.S. Department of Agriculture's (USDA) agriculture soil texture classification to the USDA's soil particle size classification. (a 2007 revision)

Pages E-1 and vii (deleted "For Soil" from the title of Appendix E).
Page D-5 of Appendix D (corrected the terms and sample calculations in the 1st, 4th, 5th, 6th and 7th equations on this page). Note that this page has also been changed in the pdf presenting the entire guidance document on this webpage, and the pdf on this webpage presenting Appendix D.

Guidance for Superfund Volume I: Human Heatlh Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) (PDF) (156 pp, 3.8MB)

The link above is a large pdf for the entire guidance document.

The below links are for viewing/downloading one section at a time.

Sections

- Title page and Preface (PDF) (3 pp, 136K)
- Table of Contents (PDF) (3 pp, 107K)
- Exhibits (PDF) (4 pp, 127K)

You will need Adobe Reader to view some of the files on this page. See EPA's PDF page to learn more.

- Acronyms / Abbreviations (PDF) (4 pp, 111K)
- Chapter 1:
  Introduction and Flowchart (PDF)(5 pp, 909K)
- Chapter 2:
  Hazard Identification (PDF)(2 pp, 89K)
- Chapter 3:
  Exposure Assessment (PDF)(21 pp, 491K)
- Chapter 4:
  Toxicity Assessment (PDF)(8 pp, 82K)
- Chapter 5:
  Risk Characterization (PDF)(7 pp, 85K)
- Chapter 6:
  Conclusions/Recommendations (PDF)(3 pp, 52K)
- References (PDF) (6 pp, 71K)
- Appendix A:
  Water Pathway (PDF)(40 pp, 543K)
- Appendix B:
  Screening Tables and Reference Values for the Water Pathway (PDF) (21 pp, 645K)
- Appendix C:
  Soil Pathway (PDF)(18 pp, 499K)
- Appendix D:
  Sample Screening Calculations (PDF) (9 pp, 342K)
- Appendix E:
  Discussion on Evaluating/Developing Site-Specific Dermal Absorption Data (PDF) (2 pp, 77K)
- Part E Spreadsheets:
  - Organic Chemicals in Water (Excel)(XLS, 1.2MB) | PDF Version(23 pp, 2.5MB)
  - Inorganic Chemicals in Water (Excel)(XLS, 734K) | PDF Version(2 pp, 89K)

Implementation and Use of the Guidance

In the development of Part E, the EPA also developed and released this implementation memorandum which provides additional information about the intended use of this guidance on Superfund sites.

"Supplemental Guidance for Dermal Risk Assessment," Part E of Risk Assessment Guidance for Superfund, Human Health Evaluation Manual (Volume I) (PDF)(4 pp, 35 K, About PDF)

Questions regarding the use or application of Part E can be directed to EPA toxicologists or risk assessors in EPA's Regional Offices, or to members of the workgroup that developed this guidance. Users of the Part E guidance from outside of EPA are asked to coordinate the use of Part E on Superfund sites with the EPA Regional Office in which that site is located.

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Future Developments

This website will be used to provide guidance on implementation issues associated with the Part E guidance and to post new developments in dermal absorption science as well as updated and additional dermal default values. Thus, users of the Part E guidance should recognize that some of the values presented in the original version of Part E

may be superceded by or replaced with newer values on this website. The new dermal absorption data posted below on this website may be considered a supplement to the Part E guidance.

EPA will continue to review the peer-reviewed literature and results of EPA-sponsored research on additional default values, which will be posted on this website. EPA encourages the scientific community to conduct dermal research studies that will improve the Part E guidance and urges researchers to discuss their study protocols with EPA preferably in advance of the study to increase the likelihood that EPA will endorse their results.

Table 1. Additional and Current Dermal Absorption Fraction Values for Soil (ABSd) (Supplementing Exhibit 3-4 of Part E, last update: September 2004)

Contaminant	New ABSd Value[1] (in Per Cent)	Source of New Data[2]
Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)	1.5	Reifenrath, W.G. et al., 2002
Thiodiglycol	0.75	Reifenrath, W.G. et al., 2002
Trinitrobenzene	1.9	Reifenrath, W.G. et al., 2002
2,4-Dinitrotoluene (2,4-DNT)	10.2	Reifenrath, W.G. et al., 2002
2,6-Dinitrotoluene (2,6-DNT)	9.9	Reifenrath, W.G. et al., 2002
2-Amino-4,6-dinitrotoluene (2A, 4,6-DNT)	0.6	Reifenrath, W.G. et al., 2002
4-Amino-2,6-dinitrotoluene (4A, 2,6-DNT)	0.9	Reifenrath, W.G. et al., 2002
2,4-Diamino-6-nitrotoluene (2,4-DA-6-NT)	1.1	Reifenrath, W.G. et al., 2002
2,6-Diamino-4-nitrotoluene (2,6-DA, 4-NT)	0.5	Reifenrath, W.G. et al., 2002
Trinitrotoluene (TNT)	3.2	Reifenrath, W.G. et al., 2002
Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine (HMX)	0.6	Reifenrath, W.G. et al., 2002
Tetryl (N-methyl-N, 2,4,6-tetranitrobenzamine)	0.065	Reifenrath, W.G. et al., 2002

[1] The values presented are experimental mean values.
[2] Data sources: Reifenrath, W.G. et al. 2002 "Percutaneous Absorption of Explosives and Related Compounds: An Empirical Model of Bioavailability of Organic Nitro Compounds from Soil" *Toxicology and Applied Pharmacology*, Vol 182, pp 160-168.

Additional Information

While not developed by the Office of Solid Waste and Emergency Response or our dermal risk assessment workgroup, we nevertheless have found some additional information relevant to dermal risk assessments that we make available here.

In Vitro Dermal Absorption Rate Testing of Certain Chemicals of Interest to the Occupational Safety and Health Administration | PDF Version (40 pp, 230K, About PDF)
This is a final rule that provides an invitro testing protocol and that requires companies producing certain chemicals to conduct those tests.

In Vitro Dermal Absorption Rate Testing of Certain Chemicals of Interest to the Occupational Safety and Health Administration | PDF Version (40 pp, 230K, About PDF)
This is a final rule that provides an invitro testing protocol and that requires companies producing certain chemicals to conduct those tests.

To view the test results of the chemicals described at the above link, go to Regulations.gov and enter **OPPT-2003-0006** in the search field.

Skin Exposures & Effects
This Web site contains information on dermal risk assessments, provided by the National Institute for Occupational Safety and Health (NIOSH).

Last updated on Tuesday, July 31, 2012