



Assessing Compounds without Formal Toxicity Values Available for Use in Human Health Risk Assessment

This Technical Decision Compendium was developed to provide information about databases and other resources for evaluating the toxicity of chemicals for which reference toxicity values have not been formally developed by U.S. EPA – Integrated Risk Information System (IRIS).

Background

The main sources of information on the toxicity of chemical compounds applicable to human health risk assessments include U.S. EPA's IRIS, ORD's Provisional Peer Reviewed Toxicity Values (PPRTVs), U.S. EPA's Health Effects and Assessment documents and Summary Tables (HEAST), U.S. Center for Disease Control Toxicological Profiles compiled by the Agency for Toxic Substances and Disease Registry (ATSDR), and International Agency for Research on Cancer (IARC) monographs. Quantitative toxicological criteria include regulatory and advisory values developed by U.S. EPA, Ohio EPA, ATSDR, California EPA (CalEPA), the American Conference of Governmental and Industrial Hygienists (ACGIH), the American Industrial Hygiene Association (AIHA), the National Institute of Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA).

Decision

The primary source of toxicity information applicable to human health risk assessments, used by both the U.S. EPA Superfund Program (U.S. EPA, 1989; 2003) and the Ohio EPA Division of Environmental Response and Revitalization - DERR (RRP and Voluntary Action Program, VAP, 2002), is **IRIS** <http://www.epa.gov/iris/index.html>. However, many chemicals have no formally developed toxicity reference values and are not listed in IRIS data base.

For chemicals without formally developed toxicity values, district office staff will task the Ohio EPA - DERR Central Office to determine the appropriate toxicity information for use in a human health risk assessment. In general, and in accordance with the U.S. EPA - OSWER Directive (2003), the following hierarchy of additional sources may be used to determine the most appropriate toxicity information if not available in IRIS:

- U.S. EPA Office of Research and Development PPRTV. These peer-reviewed toxicity values will gradually replace HEAST values. Although PPRTVs are no longer publically accessible on the Internet (point of contact: Dave Crawford in EPA/OSRTI at Crawford.Dave@epa.gov). For sites related to the Superfund Program, additional assistance may be obtained from the EPA Superfund Health Risk Technical Support Center (STSC), tel. 513-569-7300, e-mail: STSC.Superfund@epa.gov or National Center for Environmental Assessment (Director of STSC, NCEA-Cincinnati, tel. 513-569- 7536), or from the assigned contact in the U.S. EPA Region 5.
- In the case where PPRTVs are not available and the Region 5 and/or NCEA cannot provide any provisional toxicity values, the following resources may be explored:
- California Environmental Protection Agency toxicity values (peer reviewed: <http://www.oehha.ca.gov/risk/chemicalDB//index.asp>);
- U.S. CDC - ATSDR Toxicological Profiles (peer reviewed: <http://www.atsdr.cdc.gov/mrls/index.html>);
- HEAST values (not yet peer reviewed);
- U.S. EPA Criteria Documents (the documents include but are not limited to: drinking water criteria documents; drinking water health advisory summaries; ambient water quality criteria documents; and air quality criteria documents).
- If still no appropriate toxicity values are available, Ohio EPA may require that in lieu of a quantitative health risk assessment, a qualitative evaluation of chemical toxicity at concentrations and intakes relevant to the site may be performed, described as a narrative, and discussed under the UNCERTAINTY section of the remedial investigation (RI) report or baseline risk assessment (BRA) document.

Ohio EPA - DERR **does NOT recommend** that Potentially Responsible Parties (PRPs) and/or their Contractors attempt to derive toxicity values for the quantitative human health risk assessments of chemicals.

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Rationale

The recommended hierarchy of resources for toxicity values, is essentially the same as in the tiered system provided by U.S. EPA - OSWER Directive (2003) for Superfund. When no formal toxicity value is available in IRIS, no PPRTV is available, no provisional value is provided by NCEA and no reliable quantitative information can be found, the Ohio EPA - DERR may permit qualitative information about the chemical toxicity at concentrations and intakes relevant to the site. The following are the examples of additional resources that may be helpful in locating relevant information:

U.S. Federal or State government Internet resources:

- Toxicological Profiles ATSDR <http://www.atsdr.cdc.gov/toxpro2.html>
- Toxicity Profiles RAIS http://rais.ornl.gov/tools/tox_profiles.html
- Search of NTP Toxicity Studies Database http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm
- U.S. EPA List of Drinking Water Contaminants & MCLs <http://www.epa.gov/safewater/mcl.html>
- Ohio Administrative Code rule 3745-300-01 <http://www.epa.ohio.gov/portals/30/SABR/docs/Rules/3745-300-08.pdf>
- U.S. EPA Regional Screening Levels and Region 9 Preliminary Remediation Goals <http://www.epa.gov/region09/superfund/prg/index.html>
- U.S. EPA Region 3 Risk-Based Concentrations http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm
- ATSDR Minimal Risk Levels (MRLs) http://www.atsdr.cdc.gov/mrllist_01_03.pdf

Other sources:

- Generally accepted textbooks of toxicology (e.g., Casarett and Doull's 'Toxicology The Basic Science of Poisons')
- TERA -ITER Database <http://www.tera.org/iter/>
- RiskIE: <http://www.allianceforrisk.org/RiskIE.htm>
- International Programme on Chemical Safety (IPCS) <http://www.inchem.org/>
- National Library of Medicine - Toxnet and Hazardous Substances Databank: <http://toxnet.nlm.nih.gov/>
- <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>
- Some, usually limited, information about toxicity may be found at the chemical manufacturer's Material Safety Data Sheet (MSDS) <http://www.ilpi.com/msds/index.html>

Contact

For more information, contact First Last at Brian.Tucker@epa.ohio.gov or (614) 644-3120.

References

Casarett and Doull's 'Toxicology, The Basic Science of Poisons', Klaassen, C.D., Amdur, M.O., and Doull, J., Eds., McGraw-Hill, New York, 1996.

U.S. EPA, Office of Emergency and Remedial Response: 'Risk Assessment Guidance for Superfund', Volume 1, 'Human Health Evaluation Manual: Parts A to F. Available on-line: http://www.epa.gov/oswer/riskassessment/superfund_hh_exposure.htm

U.S. EPA, Office of Solid Waste and Emergency Response. OSWER Directive 9285.7-53 'Human Health Toxicity Values in Superfund Risk Assessments'. December 5, 2003. Available on-line: <http://www.epa.gov/oswer/riskassessment/pdf/hhmemo.pdf>

U.S. EPA, Office of Research and Development, Office of Superfund Remediation and Technology Innovation. 'Provisional Peer Reviewed Toxicity Values for Superfund (PPRTV) Database'.

VAP - Ohio EPA, Division of Emergency and Remedial Response, Voluntary Action Program - 'Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures', August 2008. Available on-line: <http://www.epa.ohio.gov/portals/30/vap/docs/support%20doc%20version.pdf>