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Engineering & Scientific Consulting

Keith Morris-Schaffer, Ph.D., DABT, ERT

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Professional Profile

Dr. Morris-Schaffer is a board-certified global toxicologist who provides a range of regulatory toxicology and product stewardship services for clients including safety assessments for proactive product applications for chemicals and medical devices as well as for reactive matters such as regulatory data call-ins and product recalls. Dr. Morris-Schaffer specializes in weight-of-evidence evaluations in which in vitro (cell-based testing), in vivo (animal testing), and clinical data are integrated to determine how a chemical or mixture elicits its effects and at what dose. Dr. Morris-Schaffer applies multiple tools to assist with toxicological risk assessments including benchmark dose modeling (BMD), quantitative structural activity relationships (QSAR), read-across, and New Approach Methodologies (NAMs).

Dr. Morris-Schaffer has working familiarity with multiple regulatory frameworks including for medical devices (ISO 10993 and 18562), pharmaceutical impurities (ICH), pesticides (FIFRA), industrial chemicals (e.g., REACH, TSCA), consumer (FHSA, Proposition 65), and food additives (FFDCA). He has addressed complex and multi-disciplinary projects for clients including carcinogenicity, neurotoxicity, and reproductive/endocrine matters that involved both written submissions and verbal presentations to regulators. He has prepared fit-for-purpose weight of evidence analyses tailored to support stewardship, registration or re-evaluation efforts for compounds under each regulatory framework. He has also provided guidance for human health claim substantiation and occupational exposure levels including support for product labels, use directions, and Safety Data Sheets.

His research background is inhalation of ultrafine (nano) particles and their potential effects on developmental neurotoxicity, and he has provided technical guidance to clients on respiratory and neurotoxicity toxicological outcomes of environmental chemicals.

Academic Credentials & Professional Honors

Ph.D., Toxicology, University of Rochester, 2019

M.S., Toxicology, University of Rochester, 2016

B.A., Psychology, SUNY Geneseo, 2014

Exponent 2021 Excellence Award

Licenses and Certifications

Diplomate of the American Board of Toxicology (DABT)

European Registered Toxicologist

UK Reg of Toxicologists

Professional Affiliations

National Society of Toxicology (SOT) - 2024-present Full Member

National Society of Toxicology (SOT) - 2019-2024 Associate Member

Genetic and Environmental Toxicology Association of Northern California (GETA) - Board 2020-2023

Publications

Morris-Schaffer, K., Farrington, H., Dahlberg, S., Llewellyn, C., Freeman, E., 2025 A systematic literature review and weight of evidence evaluation of the genotoxicity potential of atrazine. Journal of Toxicology and Regulatory Policy, 1(2), pp. 1–39.

Morris-Schaffer, K., Dahlberg, S., Johann, E., Murphy, M.M., Tran, N.L. and Freeman, E.L., 2025. Preclinical safety evaluation of sodium L-methylfolate. Food and Chemical Toxicology, p.115822.

Scrafford, C.G., Davis, B.J.K., Higgins, K.A., Moynihan, E., Morris-Schaffer, K., Anderson, M., Rackl, S.M., Hearon, S. and Davis, D., 2025. Estimated Long-Term Dietary Exposure to Cadmium from Consumption of Spinach in the United States: A Probabilistic Assessment. Food and Chemical Toxicology, p.115269.

Morris-Schaffer, K., Higgins, L., Kocabas, N.A., Faulhammer, F., Cordova, A., Freeman, E., Kamp, H., Nahar, M., Richmond, E. and Rooseboom, M., 2025. A weight of evidence review on the mode of action, adversity, and the human relevance of xylene's observed thyroid effects in rats. Critical Reviews in Toxicology, pp.1-26.

Faulhammer, F., Rooseboom, M., Kocabas, N.A., Arts, J.H., Cordova, A., Freeman, E., Higgins, L.G., Nahar, M., Richmond, E., Schneider, S. and Morris-Schaffer, K., 2024. Xylene: weight of evidence approach case study to determine the need for an extended one generation reproductive study with a developmental neurotoxicity animal cohort. Critical Reviews in Toxicology, 54(10), pp.925-952.

Moser, V.C., Morris-Schaffer, K., Richardson, J.R. and Li, A.A., 2022. Glyphosate and neurological outcomes: A systematic literature review of animal studies. Journal of Toxicology and Environmental Health, Part B, 25(4), pp.162-209.

Miller-Rhodes, P., Piazza, N., Mattle, A., Teboul, E., Ehmann, M., Morris-Schaffer, K. and Markowski, V.P. Sex-specific behavioral impairments produced by neonatal exposure to MK-801 are partially reversed by adolescent CDPPB treatment. Neurotoxicology and teratology, 2022, 89, p.107053.

Morris-Schaffer, K and McCoy, MJ. "A Review of the LD50 and Its Current Role in Hazard Communication." ACS Chemical Health & Safety. 2021. 28:1, 25-33. https://doi.org/10.1021/acs.chas.0c00096

Edwards CM, Small D, Bell T, David-Drori J, Hansen C, Morris-Schaffer K, Canale C, Ng J, Markowski VP. Early postnatal decabromodiphenyl ether exposure reduces thyroid hormone and astrocyte density in the juvenile mouse dentate gyrus. Physiology & Behavior. 2020. 216:112798.

Jew, K, Herr, D, Wong, C, Kennell, A, Morris-Schaffer, K, Oberdörster, G, O'Banion, K, Cory-Slechta, DA, and Elder, A. Selective memory and behavioral alterations after ambient ultrafine particulate matter exposure in aged 3xTgAD Alzheimer's disease mice. Particle & Fibre Toxicology 2020 16:45

Morris-Schaffer K, Merrill AK, Jew K, Wong C, Conrad K, Harvey K, Marvin E, Sobolewski M, Oberdörster G, Elder A, Cory-Slechta DA: Effects of neonatal inhalation exposure to ultrafine carbon particles on pathology and behavioral outcomes in C57BL/6J mice. Particle & Fibre Toxicology 2019. 16:10.

Morris-Schaffer K, Merrill A, Wong C, Jew K, Sobolewski M, Cory-Slechta D: Limited developmental neurotoxicity from neonatal inhalation exposure to diesel exhaust particles in C57BL/6 mice. Particle & Fibre Toxicology 2019, 16:1.

Morris-Schaffer K, Sobolewski M, Welle K, Conrad K, Yee M, O'Reilly MA, Cory-Slechta DA: Cognitive flexibility deficits in male mice exposed to neonatal hyperoxia followed by concentrated ambient ultrafine particles. Neurotoxicol Teratol 2018, 70:51-59.

Sobolewski, M, Anderson, T, Conrad, K, Marvin, E, Klocke, C, Morris-Schaffer, K, Cory-Slechta, DA. Developmental Exposures to Ultrafine Particle Air Pollution Reduces Early Testosterone Levels and Adult Male Social Novelty Preference: Risk for Children's Sex-Biased Neurobehavioral Disorders. NeuroToxicology 2018, 68:203-211

Morris-Schaffer K, Sobolewski M, Allen JL, Marvin E, Yee M, Arora M, O'Reilly MA, Cory-Slechta DA: Effect of neonatal hyperoxia followed by concentrated ambient ultrafine particle exposure on cumulative learning in C57Bl/6J mice. NeuroToxicology 2018, 67:234-244.

Allen JL, Oberdorster G, Morris-Schaffer K, Wong C, Klocke C, Sobolewski M, Conrad K, Mayer-Proschel M, Cory-Slechta DA: Developmental neurotoxicity of inhaled ambient ultrafine particle air pollution: Parallels with neuropathological and behavioral features of autism and other neurodevelopmental disorders. NeuroToxicology 2017, 59:140-154.

Allen, JL, Klocke, C., Morris-Schaffer, K, Conrad, K, Sobolewski, M, Cory-Slechta, DA: Cognitive Effects of Air Pollution Exposures and Potential Mechanistic Underpinnings. Current environmental health reports 2017, 4(2): 180-191.

Sobolewski, M, Allen, JL, Morris-Schaffer, K, Klocke, C, Conrad, K, & Cory-Slechta, DA: A novel, ecologically relevant, highly preferred, and non-invasive means of oral substance administration for rodents. Neurotoxicol Teratol 2016, 56: 75-80.

Book Chapters

Morris-Schaffer, K., 2026. Comprehensive Review of Dermal Toxicity Studies. In: McQueen, Charlene A. (ed.) Comprehensive Toxicology, 4th Edition, vol. 3, pp. 385-403. London: Elsevier.

Kalmes, R.M., Donnell, M.T., Morris-Schaffer, K. and Scrafford, C.G., 2024. Proposition 65 and Exposure Assessment Methods. Human and Ecological Risk Assessment: Theory and Practice, 1, pp.571-581.

Allen, J.L., Klocke, C., Morris-Schaffer, K., Conrad, K., Sobolewski, M. and Cory-Slechta, D.A., 2022. Air Pollution and Neurodevelopmental Disorders. Toxicology of Nanoparticles and Nanomaterials in Human, Terrestrial and Aquatic Systems, pp.237-275.

Presentations

Morris-Schaffer, K., Pecquet, A., Solomon, K., Freeman, E., and Goetz-Bouchard, A. Using new approach methods in weight of evidence, now and in the future. Poster Presentation. American Chemical Society, Annual Fall Meeting (Washington, DC & Digital), 2025.

Cordova, A.C., Morris-Schaffer, K., Chrysostomou, P., and Freeman, E. Case Study Review of Subchronic-to-Chronic Study Extrapolation Uncertainty Factor Using Benchmark Dose Analysis. Poster Presentation. Society of Toxicology, Annual Meeting (Salt Lake City) & ToxExpo, 2024.

Morris-Schaffer, K., and Bolotaolo, M. Estimation of Screening No-Significant-Risk-Level and Product Exposure to 3,3',4,4'Tetrachloroazobenzene (TCAB). Society of Toxicology, Annual Meeting (San Diego) & ToxExpo, 2022.

Kalmes, R, Krevanko, C, and Morris-Schaffer, K. Beyond Hazard Assessment for your products: Why, When, and How. Product Safety Stewardship (PSX), Annual Meeting (Anaheim) 2021.

Morris-Schaffer, K. Estimation of Screening No-Significant-Risk-Levels (NSRLs) and Product Exposure to β-myrcene and Pulegone. Poster Presentation. Society of Toxicology, Annual Meeting & ToxExpo (Virtual Event), 2021.

Morris-Schaffer, K, Bogen, K, and Gauthier, A. Evaluating Allergic Contact Dermatitis Elicitation Risk for Organic Residuals Detected in Consumer Products. Society of Toxicology, ePoster, 2020.

Morris-Schaffer, K, Merrill, A, Sobolewski, M, and Cory-Slechta, DA. Effects of Neonatal Inhalation Exposure to Ultrafine Carbon Particles and Diesel Particulate on Pathology and Behavioral Outcomes in C57Bl/6J. Poster Presentation. Genetic and Environmental Toxicology Association, Sacramento, CA, 2019.

Morris-Schaffer, K. Limited Developmental Neurotoxicity from Neonatal Exposure to Ultrafine Carbon Particles or Diesel Particulate Matter. Poster presentation, Society of Toxicology, Baltimore, MD, 2019.

Morris-Schaffer, K. Limited Developmental Neurotoxicity from Neonatal Exposure to Ultrafine Carbon Particles or Diesel Particulate Matter. Oral presentation, Northeast Regional Chapter of Society of Toxicology, Shrewsbury, MA, 2018.

Morris-Schaffer, K, Sobolewski, M, and Cory-Slechta, DA Neonatal hyperoxia followed by concentrated ambient ultrafine particle exposure leads to cumulative learning deficits in C57Bl/6J mice. Poster presentation, Society of Toxicology, San Antonio, TX, 2018.

Morris-Schaffer, K, Allen, JL, Sobolewski, M, and Cory-Slechta, DA Neurotoxicological consequences of developmental exposure to hyperoxia and air pollution: concurrent risk factors of premature birth. Poster presentation. Society of Toxicology, Baltimore, MD, 2017.

Morris-Schaffer, K, Allen, JL, Wong, C, Oberdorster, G, and Cory-Slechta, DA. Poster Presentation. Neonatal ultrafine particulate matter inhalation exposure adversely impacts white matter development. Society of Toxicology, New Orleans, LA, 2016.

Project Experience

Design and Execution of Toxicology Program

Planned, coordinated and executed a toxicology program that included prenatal development, repeat-dose toxicity, endocrine activity, and genotoxicity (in vitro and in vivo) assays as well as associated weight of evidence analyses for waivers and risk assessment to support registration of a novel biopesticide in the United States and European Union.

Pharmaceutical Chemistry, Manufacturing and Control

Prepared toxicological monographs compliant with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) to produce tenable permissible daily exposure levels for pharmaceutical residual impurities.

Medical Device

Prepared a dermal hazard safety assessment for a medical device hydrogel to address concerns regarding irritation and sensitization potential.

Developed a biocompatibility toxicological assessment report under the ISO 18562 standard to support a FDA 501(k) submission.

Produced multiple biocompatibility toxicological assessment evaluations under the ISO 10993 and ISO 18562 standards to support a response for a reactive FDA matter.

Neurotoxicity

Resolved a subchronic neurotoxicity deficiency identified by the California Department of Pesticide Regulation by preparing a methodology and study review waiver rationale.

Prepared a technical regulatory response document that clarified the neurotoxicology and associated pharmacokinetic data to support human equivalent concentrations (HECs) for use in a US EPA hazard characterization and dose-response assessment.

Prepared a developmental neurotoxicity literature review and study assessment of a conventional pesticide to address regulatory concerns regarding the appropriate point of departure to use in a risk assessment.

Product Stewardship and Safety

Participated as an integral member of a client's global stewardship safety team to improve data organization, extraction and analysis for safety assessments designed to support consumer packaged goods and occupational products registered with US EPA as well as non-registered products that were required to be compliant with CPSC and OSHA regulations.

Evaluation of Reproductive Toxicology under Proposition 65

Provided written and oral comments to the California Office of Environmental Health Hazard Assessment (OEHHA) Developmental and Reproductive Toxicant Identification Committee (DARTIC) regarding toxicity and mode-of-action for a pesticide under review for Proposition 65 prioritization.

Evaluation of Carcinogenicity under Proposition 65

Prepared a defensible technical report, including a review of regulatory precedent and best scientific practice, to support an estimated No Significant Risk Level (NSRL) to be used in a reactive litigation matter.

Regulatory Human Health Data

Prepared and reviewed toxicological and metabolism dossier sections for toxicokinetics, acute, repeat-dose, genotoxicity, reproductive, developmental, carcinogenicity, neurotoxicity, and endocrine disruption assays on pesticide active substances submitted for the European Union renewal of approval program (AIR).

Peer Reviews

Neurotoxicology