Toxicological Assessment and Physico-Chemical Characterization

Government Resources (Toxicological Assessment)

- U.S. Air Force, Air Force Research Laboratory (AFRL), Human Effectiveness Directorate, Biosciences and Protection Division

  Applied Biotechnology Branch (*in vitro* toxicology engineered nanomaterial research, etc.)

- Army Corps of Engineers (ACE) Engineering Research and Development Center (ERDC).

  Environmental Laboratory (Engineered Nanomaterial Risk Assessment: Environmental Behavior and Ecotoxicological-Related Research)

- U.S. Army Public Health Command (Provisional) Directorate of Toxicology

  – Health Effects Research Laboratory

  – Toxicology Evaluation Program

- Environmental Protection Agency

  1. Harmonized Test Guidelines

- NCI Cancer NanoLab (caNanoLab) Wiki – biomedicine

  caNanoLab Portal

- NCI Nanotechnology Characterization Laboratory

  – Assay Cascade Protocols: In Vitro and In Vivo Characterization

  – Three ASTM nanotoxicology standards were part of a inter-laboratory study using a nanoscale colloidal gold reference material

External Resources (Toxicological Assessment)

- ASTM E56 Nanotechnologies

  – ASTM E2524 - 08 Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles

- ASTM E2525 - 08 Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies

- ASTM E2526 - 08 Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells

- Dupont and Environmental Defense

1. Environmental Defense – DuPont Nano Risk Framework, June 2007

2. Warheit et. al. (2007), Development of a base set of toxicity tests using ultrafine TiO2 particles as a component of a nanoparticle risk management, Toxicology Letters 171, 99-110, 2007

- ISO TC 229 Nanotechnologies (published documents)

  - ISO 29701:2010 Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test

- ISO TC 229 Nanotechnologies (projects under development)

  - ISO/FDIS 10801 Nanotechnologies -- Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method

  - ISO/FDIS 10808 Nanotechnologies -- Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing

  - ISO/TR 16196 Nanotechnologies – Guidance on sample preparation methods and dosimetry considerations for manufactured nanomaterials

  - ISO/TR 16197 Nanotechnologies – Guidance on toxicological screening methods for manufactured nanomaterials

- Organization for Economic Cooperation and Development (OECD)

  - OECD Guidelines for the Testing of Chemicals

  - Sponsorship Programme for the Testing of Manufactured Nanomaterials

1. Countries and Stakeholders

2. No. 6 - ENV/JM/MONO(2008)13/REV, List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme

- No. 15 - ENV/JM/MONO(2009)21, Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials, 10 July 2009

- No. 24 - ENV/JM/MONO(2010)25, Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials

- No. 25 - ENV/JM/MONO(2009)20/REV, Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision

- Literature

  - Oberdorster et. al., Toxicology of nanoparticles: A historical perspective, Nanotoxicology, 1:1, 2 – 25, March 2007

  - Oberdorster, Safety assessment for nanotechnology and nanomedicine: concepts of nanotoxicology, Journal of Internal Medicine, vol. 267, pages 89-105, 2009

  - Rushton, Erik K. , et. al. Concept of Assessing Nanoparticle Hazards Considering Nanoparticle Dosemetric and Chemical/Biological Response Metrics, Journal of Toxicology and Environmental Health, Part A, 73: 5, 445- 461, 2010

  - Warheit et. al. (2007), Development of a base set of toxicity tests using ultrafine TiO2 particles as a component of a nanoparticle risk management, Toxicology Letters 171, 99-110, 2007

- Presentations

  1. Castranova, V., Overview of Current Toxicological Knowledge of Engineered Nanoparticles, Conference Presentation at "Nanomaterials and Worker Health: Medical Surveillance, Exposure Registries, and Epidemiologic Research", 21-23 July 2010

2. Society of Toxicology, Nanotoxicology Specialty Section, Presentations, October 2009

***Government Resources* (Physico-chemical characterization)**

- NCI Cancer NanoLab (caNanoLab) Wiki – biomedicine

  caNanoLab Portal

- NCI Nanotechnology Characterization Laboratory

  - Assay Cascade Protocols: Physicochemical characterization, NIST - NCL Joint Assay Protocols

- Army Corps of Engineers (ACE) Engineering Research and Development Center (ERDC)

  Environmental Laboratory (Engineered Nanomaterial Risk Assessment: Environmental Behavior and Ecotoxicological-Related Research), Characterization of surface area, particle size distribution, particle charge, spectroscopy, and composition

***External Resources* (Physico-chemical characterization)**

- Environmental Defense – DuPont Nano Risk Framework, June 2007

- ISO (projects under development)

  1. ISO/AWI TR 13014 Nanotechnologies - Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment

  2. ISO/NP TS 14101, Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method

- The Minimum Information for Nanomaterials Characterization (MINChar) Initiative

- Organization for Economic Cooperation and Development (OECD)

  – No. 6 - ENV/JM/MONO(2008)13/REV, List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme

- No. 15 - ENV/JM/MONO(2009)21, Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials, 10 July 2009

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- No. 25 - ENV/JM/MONO(2009)20/REV, Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision

- Literature

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1. Murdock et. al., Characterization of Nanomaterials Dispersion in Solution Prior to In Vitro Exposure Using Dynamic Light Scattering Technique, Toxicological Sciences 101(2), 239-253, 2008

2. Nel et. al., Toxic Potential of Materials at the Nanolevel, Science, Vol. 311, pp. 622-627, 3 February 2006.

3. Powers, et. al., Research Strategies for Safety Evaluation of Nanomaterials. Part VI. Characterization of Nanoscale Particles for Toxicological Evaluation, Toxicological Sciences 90(2), 296-303, 2006.

4. Powers, et. al., Characterization of the size, shape, and state of dispersion of nanoparticles for toxicological studies, Nanotoxicology, 1:1, 42 – 51, March 2007

5. Warheit, How Meaningful are the Results of Nanotoxicology Studies in the Absence of Adequate Material Characterization? Toxicological Sciences 101(2), 183-185, 2008.