

Recommended Minimum Physical and Chemical Parameters for Characterizing Nanomaterials on Toxicology Studies

This is a recommended minimum set of parameters, and is not intended to replace more robust guidelines from governments and organizations such as ISO and OECD

What does the material look like?

- Particle size/size distribution
- Agglomeration state/Aggregation
- Shape

What is the material made of?

- Overall composition (including chemical composition and crystal structure)
- Surface Composition
- Purity (including levels of impurities)

What factors affect how a material interacts with its surroundings?

- Surface Area
- Surface Chemistry, including reactivity, hydrophobicity
- Surface Charge

Overarching considerations

- **Stability**—how do material properties change with time (dynamic stability), storage, handling, preparation, delivery etc? Include solubility, and the rate of material release through dissolution.
- **Context/Media**—how do material properties change in different media; i.e. from the bulk material to dispersions to material in various biological matrices? (“as administered” characterization is considered to be particularly important)
- Where possible, materials should be characterized sufficiently to interpret the response to the amount of material against a range of potentially relevant dose metrics, including mass, surface-area and number concentration.

Notes

This framework is designed to stimulate appropriate characterization, while complimenting more specific guidance from organizations such as ISO and OECD.

Highlighting a key set of parameters without specifying prescriptive approaches to characterizing them is intentional, as an approach to fostering a culture of effective characterization without stifling innovation, developing a set of recommendations that are more likely to be considered by relevant communities, and allowing these recommendations to support the adoption of more authoritative guidelines from other sources. Furthermore, the intentional omission of defined methods is meant to foster discussions between researchers in the biological sciences and the materials sciences, both of which play a role in characterizing the effects of nanomaterials on biological systems.

These recommendations were developed at a workshop on ensuring appropriate material characterization in nano-toxicity studies, held at the Woodrow Wilson International Center for Scholars in Washington DC between October 28-29, 2008