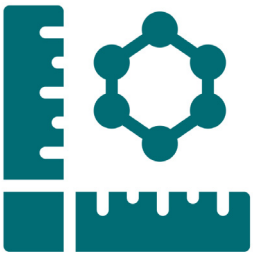
How Nanomaterials Measure Up



By Sydney Cook, M.S.

Nanoparticles (NPs) are generally defined as a particle of matter having one dimension that ranges between 1 and 100 nanometers (nm). To get a sense of the size, a human hair ranges from 50,000 to 100,000 nanometers wide. The head of a pin is one million nanometers wide. These are infinitesimal measurements unrecognizable by the human eye.

Nature has been making nanoparticles since the dawn of time, but for the purpose of this Fact Sheet, we are specifically talking about *synthetic* nanoparticles or naturally derived substances that are *intentionally processed* to become nanoscale for use in products. For example, some metal compounds and iron oxides are micronized into nanoparticles for use.

Nanoparticles are purposeful to industry for many reasons – hence nanoparticles' wide deployment for an array of common goods from apparel to appliances, foods to fragrances, medical tech to medicines. What makes them uniquely useful is that they have varying properties based on the size and surface functionality of the particle[1]. The dramatic difference in size can also cause nanoparticles of a substance to behave differently than larger particles of the same substance.[2]

MADE SAFE Determination

At MADE SAFE, we are concerned with the frequency of use of NPs as we don't believe nanomaterials have been properly assessed for human or environmental health effects. MADE SAFE does not permit ingredients that are known or *suspected* to be harmful to humans or the environment. Decisions on ingredients are made using publicly available data, data provided by manufacturers, and environmental fate and toxicity modeling.

Because data is lacking on many nanomaterials and issues have been extensively documented with some types of nanomaterials, MADE SAFE does not permit nanomaterials in Certified products.

Nanomaterial Safety

Researchers don't yet fully understand the impacts nanoparticles could have on human health and the environment. However, because of their infinitesimally small size, nanoparticles may be more chemically reactive and therefore more bioavailable.[3] In a scientific review of nanoparticles, researchers found that there are considerable concerns due to organ, DNA, mitochondrial and cellular damage from a variety of NPs[4].

In addition to safety concerns, there is minimal regulation for nanotech in the United States. As of 2017, the U.S. Environmental Protection Agency requires companies that manufacture nanoparticles to notify them.[5] Though a step in the right direction, we need comprehensive regulation for this complex issue. In the meantime, numerous new and untested nanoparticle technologies are hitting the market at an unprecedented pace.

What Is a Nanomaterial?

There is currently no scientific consensus on the definition of the precise size range of a nanomaterial. Numerous governments and authoritative agencies have created definitions, but those definitions are not yet harmonious. This is important because a lack of consensus means that there is disagreement on what is considered a nanomaterial and what is not.

The European Commission, the European Union's (EU) executive arm, has put forth a definition, defining 'nanomaterial' as: "A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate *or as an agglomerate* and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm."[6]

The EU includes not just unbound, solo particles, ***but also aggregates and agglomerates*** in their definition of nanomaterials. Aggregates and agglomerates are bound groupings of single particles. Said differently, you can think of particles as individual snowflakes and the groupings as snowballs, comprised of individual snowflakes.

The EU includes aggregates and agglomerates in their definition because: "Agglomerated or aggregated particles may exhibit the same properties as the unbound particles. Moreover, there can be cases during the life-cycle of a nanomaterial where the particles are released from the agglomerates or aggregates."[7]

According to the U.S. Food & Drug Administration (FDA) nanotechnology industry guidance, aggregates and agglomerates should be considered in nanomaterial legislation.[8] In their guidance, FDA also cites conclusions from the EU Commission as well as from the International Organization for Standardization (ISO) and Health Canada.[9]

How Nanomaterials Measure Up

MADE SAFE sets the limit at 100 nm for certified products (all non-food items), which is congruent with the 100 nm limit set forth by the European Union.[10] And because particles can be released from agglomerates and aggregates, at MADE SAFE we believe that the size of the individual particles that make up a grouping should be measured and reviewed against the size limit. If those individual particles are nanomaterials, then they should not be permitted for use in MADE SAFE Certified products – even if the aggregate or agglomerate is larger than 100 nm.

Our position is backed by the latest scientific literature and international policies, including definitions or guidance adopted by the European Union, Health Canada, U.S. Food and Drug Administration and the International Organization for Standardization.

At MADE SAFE, we take a precautionary approach. For example, when it comes to frequently used ingredients such as titanium dioxide or zinc oxide – most commonly used in sunscreen and baby care – we're particularly tough. We require two different test methods to demonstrate non-nanomaterial status. Because some manufacturers only measure the size of the aggregate or agglomerate and not the smallest particles, many of the products on the market that make a non-nano claim would not pass our rigorous specifications.

Unfortunately, the lack of harmony among rule makers, regulators and marketers leads to consumer confusion and, potentially, misleading label claims.

How to avoid nanoparticles in products:

- Shop MADE SAFE Certified products
- Look for 'non-nano' labels on packaging, as this is a springboard to start to shop better. But, merely trust 'non-nano labels' at face value. They're a great place to start, but follow up by asking companies how they measure and test for nanomaterial status. Do they measure the smallest particles in a grouping or do they measure aggregates or agglomerates as a whole? This can help you decide if it's a product you want to buy and a company you want to support.
- Some of the most common nano ingredients in personal care and cosmetics include: zinc oxide, titanium dioxide, silica, clays, and activated charcoal – so be on the lookout for these. And remember to avoid all silver – whether it's nano or non-nano. Read our Chemical Profile for more details.

Endnotes

1 Najahi-Missaoui, W., Arnold, R.D., & Cummings, B.S. (2020). Safe Nanoparticles, Are We There Yet? *International Journal of Molecular Sciences*, 22 (1), 385. 10.3390/ijms22010385

2 U.S. Environmental Protection Agency. (2017). Control of nanoscale materials under the Toxic Substances Control Act. Retrieved from https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under

3 Friends of the Earth. (2016). *Nanoparticles in baby formula: Tiny new ingredients are a big concern*. Retrieved from https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/wpallimport/files/archive/FOE_NanoBabyFormulaReport_13.pdf

4 Najahi-Missaoui, W., Arnold, R.D., & Cummings, B.S. (2020). Safe Nanoparticles, Are We There Yet? *International Journal of Molecular Sciences*, 22 (1), 385. 10.3390/ijms22010385

5 U.S. Environmental Protection Agency. (2017). Control of nanoscale materials under the toxic substances control act. Retrieved from https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under#regs

6 European Commission (2011). Commission recommendation of 18 October 2011 on the definition of nanomaterial. *Official Journal of the European Union*, 285(39). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696&from=EN

7 European Commission (2011). Commission recommendation of 18 October 2011 on the definition of nanomaterial. *Official Journal of the European Union*, 285(39). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696&from=EN

8 U.S. Food and Drug Administration (2014). Considering whether an FDA-regulated product involves the application of nanotechnology: guidance for industry. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considering-whether-fda-regulated-product-involves-application-nanotechnology#_ftn10

9 U.S. Food and Drug Administration (2014). Considering whether an FDA-regulated product involves the application of nanotechnology: guidance for industry. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considering-whether-fda-regulated-product-involves-application-nanotechnology#_ftn10

10 European Commission (2011). Commission recommendation of 18 October 2011 on the definition of nanomaterial. *Official Journal of the European Union*, 285(39). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696&from=EN