

EPA Has Safely Regulated Nanosilver for Decades

SNWG Contributes to Expert Scientific Panel

The Silver Nanotechnology Working Group (SNWG), an industry effort intended to foster the collection of data on silver and nanotechnology in order to advance the science and public understanding of the beneficial uses of silver nanoparticles in a wide-range of consumer and industrial products, made a detailed presentation¹ to the recent EPA Scientific Advisory Panel (SAP) meeting to discuss the topic “*Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Oxide Pesticide Products*” (Arlington VA, November 3-6, 2009)². Key conclusions from the presented analysis include:

Nanosilver: Over 100 years old

Nanosilver is not a new material. The assumption of nanosilver being a new material with fears of new properties and new unknown hazards is at the heart of both regulatory and many popular perceptions about nanosilver. However, contrary to assumptions of newness, nanosilver materials are old and have been well known throughout the ages. Indeed, nanosilver has been rationally manufactured and used commercially for over a century.

Many different terminologies have been used throughout scientific history to describe ultrasmall silver particles including "colloidal silver", "millimicron silver" and among other terms the current "nanosilver" terminology. Accordingly, while the term “nanosilver” is new, the technology it represents is not.

The SNWG provided the SAP meeting with a detailed historical and technical analysis that demonstrated that these materials have a long established commercial history as engineered particles of nanoscale size.¹ Despite changes in terminology, the underlying material being described is in fact the same that has been used for decades. i.e. nanoscale silver.

EPA has a long history of safely regulating nanosilver

The EPA has been safely and successfully regulating nanosilver products for decades. These products have been used in a wide range of consumer applications such as swimming pool treatments and drinking water filters with an established record under FIFRA of regulated and safe use dating as far back as the 1950’s.

A detailed look at the depth of history of silver within the EPA shows that the toxicological studies that form the basis of the EPA’s general hazard limits for silver derive from historical data from nanoscale silver materials and not ‘conventional (bulk) silver’ as is often mistakenly assumed.

A careful examination of the EPA public registration database³ for silver over a period of 6 decades reveals:

- The very first registered silver product was a colloidal nanosilver algaecide product that has been safely used by millions of consumers for over 50 years (registered since 1954).

¹ SNWG “Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Oxide Pesticide Products”, Presentation to Scientific Advisory Panel (November 4th, 2009).

<http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480a52512&disposition=attachment&contentType=pdf>

² EPA Scientific Advisory Panel meeting, Arlington VA (November 3 - 6, 2009), <http://www.epa.gov/scipoly/sap/meetings/2009/november/110309aagenda.pdf>

³ NPIRS Public. <http://ppis.ceris.purdue.edu/npublic.htm>

- Every EPA silver registration between 1970 and 1990 was either a colloidal nanosilver or nanosilver-composite product.
- The very first NON-nanosilver product registered by EPA was not registered until 1994.
- An overall analysis reveals that today over 50% of all EPA registered silver products are in fact based on nanoscale silver.

Regulatory Relevance

EPA has a range of existing regulatory structures that have successfully addressed silver materials across the size spectrum for over 5 decades. Throughout this period, the EPA has not recorded any incidents of significance on the Agency's formal incident reporting database (EPA OPP IDS) – indicating that thorough monitoring of real-life use supports the safety of these products.

The EPA should be congratulated for this record of successful monitoring and risk management for these materials despite different terminologies being used throughout this period of time.

Indeed, given that with nanosilver there is perhaps more historical data and evidence of safe use than for many other regulated materials, EPA has the opportunity to assess nanosilver products with confidence given this long history of safe use under existing EPA regulations.

The following themes are vital for consideration of an informed regulatory approach:

Nanosilver is NOT a new material - EPA needs to look beyond general conceptions of nano terminology and consider the broader established regulatory record of nanoscale silver products within the Agency.

Nanosilvers have seen decades of safe use in real-life - Given the long history of safe use for EPA-registered nanoscale silver products (stretching back as far as 1954) calls for treatment of nanosilver as a new material requiring development of expensive new test regimes and discriminatory regulatory consideration are difficult to justify.

November 24, 2009 For further details contact:
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