



Comments from the Natural Resources Defense Council
for the November 3-6, 2009
FIFRA Scientific Advisory Panel (SAP) Session
Entitled
**“Assessment of Hazard and Exposure Associated with
Nanosilver and other Nanometal Pesticide Products”**

Docket ID# EPA-HQ-OPP-2009-0683

The Natural Resources Defense Council (NRDC) is a national, nonprofit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Founded in 1970, NRDC has 1.2 million members and online activists, served from offices in New York, Washington, Chicago, Los Angeles, San Francisco and Beijing. We have no financial interest in the manufacture or sale of any nanomaterials or any pesticide products.

NRDC recommends that the SAP reject using a strict size definition for nanomaterials (such as 1 to 100 nm) as being unscientific and inappropriate for regulatory purposes. There is no scientifically-defensible bright line where a material becomes “nano” or “normal” scale with regards to its toxicology. In addition, these particles often occur together in mixtures with a range of sizes and therefore we expect that humans and the environment would be exposed to a wide suite of particle sizes. Nanomaterials are intentionally engineered to take advantage of unique properties at the nanoscale. The physical and chemical properties of nanoscale materials, such as reactivity, persistence, or bioavailability, can differ significantly from their larger scale counterparts. Any or all of these size-dependent properties may impart changes in toxicity that are poorly characterized.

NRDC recommends that the SAP direct EPA to require size-appropriate safety data for any material that is intentionally engineered to have size-dependent properties. The potential hazards associated with exposure to nanosilver and other nano-metals are likely to differ from their conventionally-sized counterparts. Unless data from multiple, well-designed studies with adequate statistical power demonstrate otherwise, materials that are intentionally designed to have unique physical properties associated with their small size should be presumed to have a unique size-dependent toxicity profile.

NRDC recommends that the SAP direct EPA to require that any pesticidal products that incorporate chemical ingredients or components that are intentionally

engineered to take advantage of unique properties associated with small size should be disclosed and accompanied by a full suite of size-specific safety testing data.

NRDC recommends that the SAP discuss other nano-metal pesticides that are commercialized, but not yet registered or safety tested. For example, Osmose, Inc., a wood preservation technologies company, advertizes nano-scale “micronized” copper-based biocides for wood treatment. A product report on their website confirms that an analysis of the treated wood “revealed the presence of nano-sized copper and iron particles (from grinding media) ranging from 10 to 700 nm in micronized treated wood....”¹ This product is already in widespread use; a 2009 media release from the manufacturer on the safety and performance of micronized copper technology boasts that “over 5 billion board feet of MicroPro treated wood has been sold since the product introduction in 2006.”² The company claims that its micronized technologies are certified as an Environmentally Preferable Product (EPP), suggesting that its products are safe for the environment.³ However, it appears that EPA has never been provided with any safety data for the nano-scale “micronized” formulation of this wood treatment biocide. This is the type of information that should be provided to the EPA before an untested nano-material is allowed to flood the market.

NRDC recommends that the SAP consider the effect of agglomeration on toxicity. Agglomeration is likely to be a significant influence on toxicity, at least for some nanomaterials. An EPA funded study by researchers from the New York University Nelson Institute of Environmental Medicine (Gordon et al, 2008) exploring the role of particle agglomeration on nanoparticle toxicity reported that particle composition as well as size affected toxic properties.⁴ The researchers tested inbred BALB/c mice exposed by inhalation. Inhaled freshly generated carbon nanoparticles (11-60 nm range) produced much greater lung inflammation than the larger-sized aged carbon nanoparticles (150-250 nm). Under identical test conditions, copper and zinc nanoparticles showed less of a difference between fresh and aged, but both metals produced 3-fold more inflammation and lung injury (measured by protein) than carbon nanoparticles. Even the larger-sized aged and agglomerated copper nanoparticles (approximately 200 nm diameter) produced significantly more lung inflammation than freshly generated carbon nanoparticles of a comparatively smaller size (11-60 nm). Thus, for carbon nanoparticles, fresh versus aged was a significant factor in toxicity, whereas for the metal nanoparticles this was less of a factor.

NRDC recommend that the SAP direct EPA to consider the age of exposure when calculating the potency of hazardous nanomaterials. The EPA-funded study by Gordon et al (2008) found a significant difference in the toxicity of inhaled nanoparticles on young versus old mice which varied depending on the inbred strain of mice. The old (8-12 mos) mice were more sensitive than the young (2-3 mos) adult mice in three inbred strains, but the opposite was true in the BtBr strain.⁵ Age-related sensitivity and genetics may be a very significant factor in the toxicity of inhaled metal nanoparticles and must be considered when assessing the safety of nanomaterials.⁶

NRDC recommends that the SAP direct EPA to consider exposures to infants and children through the use of nanosilver and other nano-chemical antimicrobials not only on food as required by federal law, but also in food contact materials and other products that children come into contact with. Nano-silver containing products now available in the US include, but are not limited to the following products that children are likely to be exposed to:⁷

<i>Product name (manufacturer)</i>	<i>antimicrobial claims</i>
Benny the Bear plush toy (Pure Plushy)	"Pure Plushy combines the use of Memory Foam and Silver Nanotechnology to form the perfect stuffed toy for children with allergies!"
Germ Slayer liquid mineral supplement (Aluwe, LLC)	"Kills virus and bacteria... Extremely tiny. The size of 2 atoms"
American Biotech Labs mineral supplement	"This new technology kills bacteria by catalytic action...It is composed of colloidal silver and high purity water...particle size 10 nm"
Nano-silver infused gold plated curling irons (Andis Co, Inc)	"Nano-Silver infusion of "Real Silver" kills bacteria"
Fresh box silver nanoparticle food storage containers (BlueMood Goods LLC)	"The naturally anti-fungal, anti-bacterial and anti-microbial properties of the finely dispersed nanosilver particles permanently imbedded in the containers"
Champion® O2 Cool™ clothing (Champion)	"Our antimicrobial lining fights the growth of odor-causing bacteria, mold and mildew on the garment"
NanoSil™ 80 swimming pool algaecide (Conseal International, Inc.)	"It contains 0.80% elemental nano-silver and 99.20% inert ingredients....At the recommended levels, NanoSil™-80 will kill most types of algae including Phormidium (Black Algae)."
NanoSil™ homeopathic silver spray gel	"It is effective for minor skin irritations, rashes hives, insect bites, sores, burns, inflammation, skin swelling and dry, itchy, cracked skin"

The special sensitivities of children and infants is recognized by the Food Quality Protection Act (FQPA). When registering pesticides, including antimicrobials, the FQPA explicitly requires EPA to assess the risk that a pesticide poses specifically to infants and children. 21 U.S.C. § 346a(b)(2)(C). Before EPA can establish a maximum allowable pesticide residue on a food (a "tolerance"), the agency must "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to the pesticide, and shall "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." *Id.* §§ 346a(b)(2)(C)(ii)(I) & (II). In ensuring that the statutory safety standard is met, EPA must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." *Id.* § 346a(b)(2)(C)(i)(II). EPA must also base its tolerance decision on available information about food consumption patterns unique to infants and children and the "cumulative effects on infants and children of [pesticides] that have a common mechanism of toxicity." *Id.* §§ 346a(b)(2)(C)(i)(I) & (III).

The special considerations of the impact on children and infants must be incorporated into EPA's assessment of these unique materials.

Thank you for consideration of these recommendations, and for your service to this SAP.

Respectfully,
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¹ A comprehensive review of copper-based wood preservatives with a focus on micronized or dispersed copper systems. MH Freeman and CR McIntyre. 2008. Forest Prod. J. 58(11): 6-27.
<http://www.osmosewood.com/micropro/images/Nov08-FPJ-Feature.pdf>

² Osmose and MicroPro media release. Consumer safety and product performance of micronized copper technology confirmed. February 10, 2009.
www.osmosewood.com/pressroom/images/Osmose%20Press%20Release%20Feb%2010%202009.pdf

³ Osmose and MicroPro media release. Consumer safety and product performance of micronized copper technology confirmed. February 10, 2009.
www.osmosewood.com/pressroom/images/Osmose%20Press%20Release%20Feb%2010%202009.pdf

⁴ Gordon, T., Lung Chi, C., Cohen, Beverly S. Final Report: Role of particle agglomeration in nanoparticle toxicity. EPA Grant No. R832528. 2008.
http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F

⁵ Gordon, T., Lung Chi, C., Cohen, Beverly S. Final Report: Role of particle agglomeration in nanoparticle toxicity. EPA Grant No. R832528. 2008.
http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F

⁶ Gordon, T., Lung Chi, C., Cohen, Beverly S. Final Report: Role of particle agglomeration in nanoparticle toxicity. EPA Grant No. R832528. 2008.
http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F

⁷ Project on Emerging Technologies, Woodrow Wilson Center. Nanosilver products database.
<http://www.nanotechproject.org/inventories/consumer/>